





NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 1
January 7, 1994

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NOTICES

REVISED PAYBACK AGREEMENT FORMS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

P.T.

National Institutes of Health
Agency for Health Care Policy and Research
Health Resources and Services Administration

Revised Payback Agreement Forms (PHS 6031, rev. 9/93) are available and must be completed by all trainees and fellows upon initiation of their first twelve months of postdoctoral National Research Service Award (NRSA) support. Previous versions of PHS 6031 will not be accepted for appointments to research training grants starting on or after February 1, 1994. Similarly, individuals receiving individual postdoctoral fellowship awards with issue dates on or after February 1, 1994 will receive and must complete the 9/93 version of PHS 6031.

The 9/93 version of PHS 6031 will permit full implementation of Section 1602 of the NIH Revitalization Act as described in the NIH Guide for Grants and Contracts (Vol. 22, No. 27, July 30, 1993). By signing these forms, recipients of postdoctoral NRSA support agree to engage in a month of health-related research, health-related teaching, or health-related research training (including NRSA-supported training) for each month of postdoctoral NRSA research training support received during the first 12 months. Therefore the maximum obligation for any postdoctoral trainee or fellow beginning NRSA training on or after June 10, 1993 is 12 months.

PHS awarding components will be mailing a supply of new agreements to training grant program directors in time for February start dates. Individual fellows will receive the new agreement with their award notice. Additional copies of the 9/93 revision of PHS 6031 are available from the Office of Administrative Services, Division of Research Grants,

Questions about this policy should be directed to the cognizant program and grants management contacts within the various PHS awarding components.

INQUIRIES

REMINDER: Program directors and institutional business officials are reminded that timely submission of all appropriate forms, including the Statement of Appointment Form (PHS 2271), the Payback Agreement Form (PHS 6031) where appropriate, the Statement of Non-Delinquency on Federal Debt (PHS T-600), and the Termination Notice (PHS 416-7) is required and critically important, especially where a service payback obligation exists. The NIH further requests that all predoctoral and postdoctoral trainees that BEGAN APPOINTMENTS PRIOR TO JUNE 10, 1993 submit a signed Termination Notice at the end of their current appointment, even if they expect to be reappointed. This form will serve as the basis for determining the total payback obligation incurred before the implementation of the NIH Revitalization Act.

NIH GRANT SUPPORT MECHANISMS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

P.T. 22, 34, 44; K.W. 1014006

National Institutes of Health

The Institutes and Centers (ICs) at the National Institutes of Health (NIH) employ many award mechanisms to support the extramural research agenda. The mechanisms for which each IC currently accepts applications differ. Therefore, the NIH will periodically publish a list of the activity codes for mechanisms in use by all ICs (Section 1) and a list of activity codes that are selectively used by ICs (Sections 2 and 3). By consulting this list, a Principal Investigator may confirm, prior to preparation of an application, whether or not an IC supports a particular mechanism.

Unique eligibility requirements may apply and special application procedures must be used for several of the types of grants. Also, some ICs accept applications for certain grant mechanisms only when solicited by a Request for Applications (RFA). Therefore, applicants are encouraged to contact IC program staff prior to the preparation of a grant application, particularly if the requested budget exceeds \$500,000.

All activity codes listed in Sections 1, 2, and 3 are also shown with the name of the mechanism in Section 4.

Section 1. The following activity codes are supported by all institutes and centers (except the Fogarty International Center and the National Library of Medicine):

F32, R01, R15, R29, R41, R42, R43, and R44

Section 2. Activity codes supported by the indicated institutes and centers:

National Institute on Alcohol Abuse and Alcoholism (NIAAA) - F30, F31, K02, K05, K20, K21, P01, P50, R03, R13, R21, S15, T32, T35, U01, U10

National Institute on Aging (NIA) - F33, K01, K04, K07, K08, K11, K12, P01, P20, P30, P50, P60, R03, R13, R25, R35, S15, T32, T35, U01

National Institute of Allergy and Infectious Diseases (NIAID) - F31, F33, F35, K04, K06, K08, K11, P01, P20, P30, P50, R03, R13, R18, R21, R25, S15, T15, T32, T35, U01, U10, U19

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) - F33, K04, K08, K11, P01, P20, P30, P50, P60, R13, R18, S15, T32, T35

National Cancer Institute (NCI) - C06, F31, F33, K04, K07, K08, K11, K12, K14, P01, P20, P30, P50, R03, R13, R18, R21, R25, R35, S15, T32, U01, U10, U13, U19, U43, U44

National Institute of Child Health and Human Development (NICHD) - F31, F33, F35, K04, K06, K08, K12, P01, P20, P30, P50, R03, R13, R24, R25, S15, T15, T32, T35, U01, U10, U18, U54

National Institute on Drug Abuse (NIDA) - F30, F31, F34, K02, K05, K20, K21, P01, P50, R03, R13, R21, R24, R25, S15, T32, U01, U18

National Institute on Deafness and Other Communication Disorders (NIDCD) - F31, F33, K04, K08, P01, P20, P50, P60, R03, R13, S15, T32, U01

National Institute of Dental Research (NIDR) - F33, F35, K04, K11, K15, K16, P01, P20, P30, P50, R03, R13, S15, T32, T35

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) - F31, F33, K04, K08, K11, P01, P20, P30, P50, P60, R13, R21, S15, T32, T35, U01

National Institute of Environmental Health Sciences (NIEHS) - F31, K04, K07, K08, K11, P01, P30, P42, R13, R25, S15, T32, T35, U01, U45

National Eye Institute (NEI) - C06, F31, F33, K11, P30, R03, R13, R21, S15, T32, T35, U01, U10, U13

National Institute of General Medical Sciences (NIGMS) - F31, F33, F34, F36, K04, P01, P41, P50, R13, R25, S06, S14,

S15, T32, T34, T35, T36, U13

National Heart, Lung, and Blood Institute (NHLBI) - C06, F31, F33, K04, K07, K08, K14, P01, P50, P60, R03, R10, R13, R18, R25, T15, T32, T35, U01

National Center for Human Genome Research (NCHGR) - F05, F31, F33, K01, K04, P01, P20, P30, P41, P50, R03, R13, R21, R25, T15, T32, U01, U13

National Institute of Mental Health (NIMH) - F30, F31, F34, F35, K02, K05, K07, K12, K20, K21, P01, P20, P30, P50, R03, R10, R13, R18, R24, R25, S15, T32, T34, T35, U01, U09, U10

National Institute for Nursing Research (NINR) - F31, F33, K07, K08, P01, P20, P30, P50, R03, R18, R21, S15, T32, U01, U10, U18

National Institute of Neurological Disorders and Stroke (NINDS) - F33, K04, K06, K08, K12, K17, P01, P20, P50, R13, S15, T32, U01, U10

National Center for Research Resources (NCRR) - C06, G12, G20, K01, M01, P01, P20, P40, P41, P51, R03, R13, R24, R25, S03, S10, T32, T35, U01, U24, U41, U42, Y01

National Library of Medicine (NLM) - F37, G07, G08, K10, P41, P50, R01, R15, R24, R29, R43, R44, T15, U09

Fogarty International Center (FIC) - D43, F05, F06, F07, F15, F20, R03, R13, T22, T37, U01

Section 3. The Agency for Health Care Policy and Research (AHCPR), a Public Health Service Agency independent of NIH, currently supports research grants designated by the following activity codes:

F32, P01, R01, R03, R18, T32, U01

Section 4. The following is an alphabetical listing of activity codes with the name of the grant or cooperative agreement mechanism.

| | |
|-----|---|
| C06 | Research Facilities Construction Grants |
| D42 | Hazardous Waste Worker Health and Safety Training Cooperative Agreements |
| D43 | International Training Grants in Epidemiology |
| F05 | International Research Fellowship |
| F06 | Senior International Fellowship |
| F07 | NIH-French CNRS Program for Scientific Collaboration |
| F15 | Scholars-in-Residence Program |
| F20 | Foreign Funded Fellowships |
| F30 | Individual Predoctoral NRSA for M.D./Ph.D. Fellowships |
| F31 | Predoctoral Individual National Research Service Award |
| F32 | Postdoctoral Individual National Research Service Award |
| F33 | National Research Service Awards for Senior Fellows |
| F34 | MARC NRSA Faculty Fellowships |
| F35 | Intramural NRSA Individual Postdoctoral Program Appointee |
| F36 | MARC Visiting Scientist Fellowships |
| G07 | Resources Improvement Grant |
| G08 | Resources Project Grant |
| K01 | Research Scientist Development Award Research and Training |
| K02 | Research Scientist Development Award Research |
| K04 | Modified Research Career Development Awards |
| K05 | Research Scientist Award |
| K06 | Research Career Award |
| K07 | Academic/Teacher Award |
| K08 | Clinical Investigator Award |
| K10 | Special Scientific Project (NLM) |
| K11 | Physician Scientist Award (Individual) |
| K12 | Physician Scientist Award (Program) |
| K14 | Minority School Faculty Development Awards |
| K15 | Dentist Scientist Award (Individual) |
| K16 | Dentist Scientist Award (Program) |
| K17 | Career Award for Re-entry into the Neurological Sciences |
| K20 | Scientist Development Award for Clinicians |
| K21 | Scientist Development Award |
| M01 | General Clinical Research Centers Program |
| P01 | Research Programs Projects |
| P20 | Exploratory Grants |
| P30 | Center Core Grants |
| P40 | Animal (Mammalian and Non-mammalian Model), and Animal and Biological Material Resources Grants |
| P41 | Biotechnology Resource Grants |
| P42 | Hazardous Substances Basic Research Grants Program |
| P50 | Specialized Center |
| P51 | Primate Research Center Grants |
| P60 | Comprehensive Center |
| R01 | Research Project (Traditional) |
| R03 | Small Research Grants |
| R10 | Cooperative Clinical Research |
| R13 | Conference (Traditional) |
| R15 | Academic Research Enhancement Awards (AREA) |
| R18 | Research Demonstration and Dissemination Projects |

R21 Exploratory/Developmental Grants
 R24 Resource-Related Research Projects
 R25 Education Projects
 R29 First Independent Research Support and Transition (FIRST)
 R41 Small Business Technology Transfer Research Grants (STTR) Phase I
 R42 Small Business Technology Transfer Research Grants (STTR) Phase II
 R43 Small Business Innovation Research Grants (SBIR) Phase I
 R44 Small Business Innovation Research Grants (SBIR) Phase II
 R35 Outstanding Investigator Grants
 S03 Minority High School Student Research Apprentice Program
 S07 Biomedical Research Support Grant
 S10 Biomedical Research Support Shared Instrumentation Grants
 S14 Minority Biomedical Research Support Grant Program for Undergraduate Colleges
 S15 Small Instrumentation Grants Program
 T15 Continuing Education Training Grants
 T22 Institutional Research Fellowships
 T32 Institutional National Research Service Award
 T34 MARC Undergraduate NRSA Institutional Grants
 T35 NRSA Short-Term Research Training
 T36 MARC Ancillary Training Activities
 T37 Minority International Research Training Grants
 U01 Research Project (Cooperative Agreements)
 U10 Cooperative Clinical Research (Cooperative Agreements)

 U13 Conference (Cooperative Agreement)
 U18 Research Demonstration (Cooperative Agreements)
 U19 Research Programs (Cooperative Agreements)
 U24 Resource-Related Research Project (Cooperative Agreements)
 U42 Animal (Mammalian and Non-mammalian) Model, and Animal and Biological Materials Resource Cooperative Agreements
 U45 Hazardous Waste Worker Health and Safety Training Cooperative Agreements
 U54 Specialized Center (Cooperative Agreements)

INQUIRIES

Further information on may be obtained from the appropriate Institute, Center, or Division contact listed below.

Dr. Kenneth Warren
 National Institute on Alcohol Abuse and Alcoholism
 6000 Executive Boulevard
 Rockville, MD 20892
 Telephone: (301) 443-4375

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Dr. Allan Czarra
 National Institute of Allergy and Infectious Diseases
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Dr. Vincent Oliverio
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Ms. Hildegard Topper
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 Parklawn Building, Room 10-42
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 6120 Executive Boulevard, Room 400C

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National Institute of Dental Research
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Telephone: (919) 541-0131

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Telephone: (301) 594-7753

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National Center for Human Genome Research

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Dr. Milton Corn
National Library of Medicine
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Dr. David Wolff
Fogarty International Center
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NATIONAL HUMAN SUBJECTS PROTECTION WORKSHOPS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human persons and those currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes:

WEST COAST WORKSHOP

DATES: January 23-24, 1994

LOCATION
Doubletree Hotel, Pasadena, CA

SPONSORS
City of Hope National Medical Center, Duarte, CA
Charles R. Drew University of Medicine and Science, Los Angeles, CA

REGISTRATION
Ms. Donna Pearce
Administrative Secretary, IRB
City of Hope National Medical Center
Beckman Research Institute
Duarte, CA 91010
Telephone: (818) 359-8111, ext. 2700

TITLE: Ethical Issues in Human Subject Research: Catastrophic Diseases and Minorities

DESCRIPTION: This workshop is intended for physicians, nurses, pharmacists, and other health care professionals as well as administrators, members of Institutional Review Boards, students, ethicists and legal experts, and lay persons with interest and concern for human subject research. The program will address the following issues: (1) new governmental policies on human subject research; (2) resolving ethical principles in clinical research on AIDS, gene transfer, and cancer prevention trials involving catastrophic illnesses; (3) drug trials and parallel track protocols; (4) minorities as research subjects; and (5) the uncertain fate of clinical research in the current era of health care reform.

SOUTH COAST CENTRAL WORKSHOP

DATES: February 17-18, 1994

LOCATION
Fairmont Hotel, New Orleans, LA

SPONSORS
University of New Orleans - Lakefront, New Orleans, LA
Xavier University of Louisiana, New Orleans, LA

REGISTRATION
Ms. Anne O'Hearn Jakob
Office of Conference Services
University of New Orleans - Lakefront
New Orleans, LA 70148
Telephone: (504) 286-6680

TITLE: Recent Trends in Human Subjects Research

DESCRIPTION: The purpose of this conference is to explore recent issues and trends related to the protection of human subjects in research. It will provide discussions and opportunities among participants to share views on NIH's new guidelines on fetal research, the inclusion of women and minorities in research, and FDA's recent policy on enrolling women of childbearing age in drug trials.

Workshops and meetings will be conducted by faculty of more than 25 national experts whose research interests include alzheimer's disease, environmental research, women's health, human genome research, biomedical research, and others.

DATES: April 27-28, 1994

LOCATION
Magovern Conference Center, Allegheny General Hospital, Pittsburgh, PA

SPONSORS
Allegheny-Singer Research Institute, Pittsburgh, PA
Delaware State College, Dover, DE

REGISTRATION

NIH Guide for Grants and Contracts - Vol. 23, No. 1 - January 7, 1994

Ms. Kathleen Hardlicka
Continuing Medical Education
Allegheny General Hospital
320 E. North Avenue
Pittsburgh, PA 15212
Telephone: (412) 359-4952

TITLE: Contemporary Issues in Human Subject Protection

DESCRIPTION: The protection of human subjects is the fundamental responsibility of institutional review boards. Today there are many challenges facing IRBs and research investigators in accomplishing this objective. This workshop will focus on current legal, ethical, and media issues related to human subjects participating in research. Emphasis will be directed at risk assessment (including mechanisms to minimize risk), research fundamentals, regulatory updates, and a special session will address the impact of the media on biomedical research. The format for the workshop will include large and small group didactic presentations and panel discussions providing a forum for audience participation.

INQUIRIES

For further information regarding these workshop and future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene Marie Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

RESEARCH ON LYME DISEASE

NIH GUIDE, Volume 23, Number 1, January 7, 1994

P.T. 34; K.W. 0715125, 0715151

Center for Diseases Control and Prevention

The Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Diseases Control and Prevention, is pleased to announce the availability of \$2,700,000 to be used in funding the first year of a new 3-year cycle of competitive Cooperative Agreements to conduct research on Lyme disease. Public and private non-profit organizations, universities, state and local health departments and research institutes are eligible to apply. It is anticipated that Program Announcement #400 will be published in the Federal Register by early to mid-December 1993. Applications will be due in the Procurement and Grants Office at the Centers for Disease Control and Prevention in Atlanta, GA on or about January 31, 1994. Specific instructions for application format, structure, contents, mailing instructions, etc., will be detailed in the announcement.

INQUIRIES

Individual application packets may be obtained by writing to:

Mr. Locke Thompson
Centers for Diseases Control and Prevention
Procurement & Grants Office
Mailstop E18
Atlanta, GA 30333
Telephone: (303) 221-8416

NOTICES OF AVAILABILITY (RFPs AND RFAs)

EARLY DETECTION RESEARCH NETWORK

NIH GUIDE, Volume 23, Number 1, January 7, 1994

MAA AVAILABLE: NCI-CN-45580-63

P.T. 34; K.W. 0780020, 0760002, 0715035, 1002004

National Cancer Institute

The Division of Cancer Prevention and Control, National Cancer Institute (NCI), in its annual requirement to seek new sources, is soliciting proposals for the Early Detection Research Network (EDRN) to increase the number of Master Agreement (MA) Holders originally awarded under MAA No. NCI-CN-15340-04. Current MA Holders for this program are not required to submit a proposal. The Master Agreement Announcement (MAA) is issued to solicit MA holders who have knowledge in establishing a biorepository of normal premalignant and malignant tissues by collecting and storing tissues and associated fluids to identify potential cellular and molecular markers for early detection. The project will focus on tissues of the colon and rectum, lung, prostate, and urinary bladder. There will be an associated database with demographic information, exposure to potential carcinogens, and risk factors on the subjects from whom specimens have been obtained; and expertise in conducting cellular and molecular studies on these tissues with the goal of developing new procedures assessing the sequence of genetic alterations in protooncogenes, analyzing allelic deletions of suppressor genes, identifying activated oncogenes, identifying oncogene products suitable for evaluating neoplastic progression, and developing cellular and molecular markers that will identify individuals who are at high risk of cancer.

INQUIRIES

Requests for this solicitation must be in writing and reference MAA No. NCI-CN-45580-63. The Master Agreement Announcement (MAA) is now available and responses will be due approximately COB January 28, 1994. Requests are to be addressed to:

Ms. Tina Huyck
Research Contracts Branch, PCCS
National Cancer Institute
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

HERMETIC PACKAGES AND FEEDTHROUGHS FOR NEURAL PROSTHESES

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFP AVAILABLE: NIH-NINDS-94-03

P.T. 34; K.W. 0740027, 0740050, 0706000

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke (NINDS) is seeking a contract to develop and demonstrate the reliability of implantable, micro-sized, hermetic packages and feedthroughs. The micropackage is required to permit neural prostheses that utilize integrated circuits and discrete components such as microcoils and capacitors to be chronically implanted. Electrical feedthroughs from inside the package to the

biological side of the package are required. These must be compatible with high density connections to both conventional microelectrodes and thin-film microelectrodes or potentially to electrodes that are integrated as part of the micropackage. The package must be biocompatible and must protect the implanted electronics from the biological environment for periods of up to 40 years. The package should be transparent to light and radio frequency electromagnetic waves to permit power and telemetry signals to be received within the package. Personnel with established expertise in microfabrication, hermetic packaging, and biomedical engineering are needed. It is anticipated that one award will be made for a period of three years in September 1994.

This is not a Request for Proposals (RFP). The RFP was issued on December 30, 1993 and proposals are due on February 28, 1994. All responsible sources shall be considered by the agency.

INQUIRIES

To receive a copy of the RFP, submit a written request and supply two self-addressed mailing labels, to:

Contracting Officer
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
ATTN: RFP NIH-NINDS-94-03

RECOMPETITION OF THE OPERATIONS CENTER FOR THE TERRY BEIRN COMMUNITY PROGRAM FOR CLINICAL RESEARCH ON AIDS.

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFP AVAILABLE: NIH-NIAID-DAIDS-95-02

P.T. 04; K.W. 0715008, 0403004

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases has a requirement for the continuation of the Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA) Operations Center to work in partnership with a series of CPCRA research units awarded to community-based health organizations. The purpose of the five-year CPCRA Operations Center contract is to:

I. Provide scientific collaboration and technical services necessary to establish clinical expertise in the development and maintenance of community-based clinical research; II. Coordinate educational and training activities for CPCRA participants in the areas of protocols. Coordinate the planning, design, implementation and evaluation of educational and training activities and materials designed for CPCRA patients and clinicians in addition to the CPCRA Statistical Center and Clinical Site Monitoring Group staff; III. Develop and maintain a computerized database management information system (MIS) for tracking the receipt, review, development, and status of CPCRA research studies, from concept stage through site registration, protocol implementation, and subsequent amendment if needed; IV. Develop and implement systems to facilitate communications between CPCRA participants. Maintain the existing nationwide electronic mail system using a commercial electronic mail system that is user friendly and cost-effective, provides for the reliable, confidential, and efficient transfer of data and word processing files, and allows users on a NIAID network and users on a FAX network to send mail messages and files to each other; and, V. Provide administrative support for the CPCRA.

The CPCRA is a clinical research program involving community physicians and their patients in studies of treatments for HIV. A unique feature of this program is its community-based focus for evaluating the effectiveness of a broad spectrum of therapies and treatment regimens. The CPCRA is comprised of 17 research units, consisting of consortiums of primary care physicians, located in 13 cities across the United States, the CPCRA Operations Center, the CPCRA Statistical Center, and the Clinical Site Monitoring Group. The 17 research units represent significant geographic, racial, and risk group diversity. Through this diversity, the CPCRA extends greater opportunity for participation in clinical research to those persons underrepresented in traditional, university-based HIV-related studies, i.e. women, minorities, and injection drug users. In addition to the above described tasks, crisis situations will frequently demand that meetings with the Contractor be rapidly convened to discuss appropriate plans of action for specific situations. Because of this factor, it is essential that the location of the Contractor's office allows for this needed interaction.

This is an announcement for an anticipated Request for Proposals (RFP). The issuance of RFP-NIH-NIAID-DAIDS-95-02 will be available on or about January 5, 1994, and proposals will be due by 4:30 p.m., local time, on March 8, 1994. It is anticipated that one (1) contract will be awarded as a result of this solicitation. It is expected that the contract will have a five year period of performance, and a completion cost-reimbursement type contract is anticipated.

INQUIRIES

Requests for the RFP shall be directed in writing to:

Ms. Brenda Velez
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
Bethesda, MD 20892

Please provide this office with five self-addressed mailing labels. Telephone inquiries will not be honored, and all inquiries must be in writing. A short-form version of the RFP will be provided first. This includes only the Statement of Work, Reporting Requirements, and the Evaluation Criteria to be used for selection of the award. After examining

this, a full-text version of the RFP must be requested, in writing, for those offerors interested in responding. FAX requests are acceptable for full text versions of the RFP only (FAX No. 301-402-0972). All proposals from responsible sources will be considered by the NIAID. This advertisement does not commit the Government to award a contract.

APPLICATION OF DATA ON THE HLA SYSTEM TO THE DEVELOPMENT AND IMPROVEMENT OF VACCINES AND INFLUENCE OF HLA AND OTHER GENES ON RESPONSE TO VACCINES.

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFP AVAILABLE: BAA NIH-NIAID-DAIT/DMID-94-30

P.T. 34; K.W. 0740075

National Institute of Allergy and Infectious Diseases

The Genetics and Transplantation Branch of the Division of Allergy, Immunology and Transplantation, National Institute of Allergy and Infectious Diseases, promotes and supports research leading to a better understanding of the HLA system, the human major histocompatibility system, including the identification, mapping, and regulation of the HLA genes, the structure and function of the products of the HLA genes, and the role of the HLA system in regulating immune responses in health and disease. The focus of Part I of this Broad Agency Announcement is on basic research that will serve to acquire the data necessary for developing new safe and effective vaccines and for improving existing vaccines, for developing improved methods for isolating, characterizing, and assessing the immunogenic potential of HLA-bound peptides of infectious agents, for developing improved methods for modifying peptides and screening their potential for use in vaccines, for defining the mechanisms underlying regulation of the response to infection and vaccination by the HLA system, and to acquire knowledge about the factors governing the interactions between peptide and HLA molecules and between T cell antigen receptors and HLA-peptide complexes. Part II of this Broad Agency Announcement invites offerors to submit proposals for conducting population research on the role of products of HLA, T cell receptor, immunoglobulin, cytokine, complement, and other genes, in responses to immunization.

BAA NIH-NIAID-DAIT/DMID-94-30 will be available on or about January 03, 1993, and proposals will be due approximately March 8, 1994. It is anticipated that more than one cost-reimbursement contract covering one or more categories listed under the Research and Technical Objectives will be awarded for a period up to five years. This advertisement does not commit the government to award a contract.

INQUIRIES

To receive a copy of this RFP, please supply two self-addressed mailing labels. All inquiries must be in writing and addressed to the office below:

Rosemary McCabe Hamill
Contracting Officer
National Institute of Allergy and Infectious Diseases
Contracts Management Branch
Solar Building, Room 3C07
6003 Executive Blvd.
Bethesda, MD 20892

HIV VACCINE PREPAREDNESS AND PHASE III EFFICACY TRIAL SITES

NIH GUIDE, Volume 23, Number 1, January 7, 1994

SFP AVAILABLE: N01-AI-35176-JMEISTER1-94

P.T. 34; K.W. 0755015, 0715008, 0740075

National Institute of Allergy and Infectious Diseases

Abt Associates Inc., under Contract No. N01-AI-35176 with the Vaccine Trials and Epidemiology Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), requires clinical trial sites to conduct seroepidemiologic and other studies in preparation for HIV vaccine efficacy trials and collaborate in potential, future multi-center phase III trials of HIV vaccines.

Offerors must be capable of enrolling and following HIV-seronegative volunteers at increased risk of exposure to HIV in preparatory studies and subsequent efficacy trials. Contractors will recruit a cohort of at least 500 volunteers in preparatory studies, and must demonstrate a capacity to recruit 1,000 volunteers in efficacy trials, which may be undertaken in the future. Offerors must provide evidence of appropriate experience and feasible strategies for: retaining at least 90 percent of enrolled study participants during a two-year prospective study; reliably interviewing study participants regarding HIV-related risk behavior; collecting, processing, storing, and shipping of laboratory specimens; handling vaccine product that requires refrigerated storage; providing HIV pre-test and post-test counseling and referrals to relevant community services; assessing participants' attitudes about enrollment in preventive vaccine efficacy trials before and after delivery of relevant information about clinical trials and HIV vaccines; assuring compliance with regulations governing the protection of human research subjects including protection of participant confidentiality; and performing clinical assessments and documenting medical findings as required by vaccine trial protocols.

Organizations submitting proposals must respond to Solicitation for Proposal (SFP) requirements for both vaccine preparedness studies (Part A) and plans for potential future phase III efficacy trials (Part B). Proposals that address only the requirements of Part A will not be considered. Plans and budgets for Part A are to be developed for a period of performance of two years. Plans and budgets for Part B are to be developed for a period of performance of five years.

Abt Associates contemplates award of cost plus fixed fee subcontracts to successful offerors. Initial awards will support Part A studies only. Award of funds for Part B trials will be contingent upon the availability of promising vaccine candidates. Subcontract modifications to support Part B trials and associated budgets will be negotiated only after authorization by NIH to proceed with the implementation of vaccine efficacy trials. Technical evaluation of proposals will consider offerors' experience and approach to both components of the SFP (Part A and Part B).

It is anticipated that offerors will be invited to include, as an optional component of their submission, proposals for the conduct of non-vaccine HIV prevention interventions (Part C). Results of the technical review of proposals for non-vaccine prevention interventions (Part C) will not be considered in the determination of the number and size of awards for preparedness studies and efficacy trials (Parts A and B).

This is an announcement for an anticipated SFP. This notice does not commit the Government or Abt Associates Inc. to award a contract. SFP N01-AI-35176-JMEISTER1-94 will be issued on or about January 10, 1994, with a closing date for receipt of proposals tentatively set for March 10, 1994. To receive a copy of the SFP, supply Abt Associates Inc. with three self-addressed mailing labels. All inquiries must be in writing and addressed to:

A. Walker
Re: SFP-JMEISTER1-94
HPRA, Abt Associates Inc.
4800 Montgomery Lane, Suite 600
Bethesda, MD 20814

IMMUNE RESPONSES TO LYME DISEASE INFECTION AND VACCINATION

NIH GUIDE, Volume 22, Number 44, December 10, 1993

RFA AVAILABLE: AI-94-008

P.T. 34; K.W. 0715125, 0710070, 0740075, 0710075

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: February 7, 1994
Application Receipt Date: March 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for research on host immune responses to infection by the etiologic agent of Lyme disease, *Borrelia burgdorferi*, and research on candidate vaccines for Lyme disease. Research focusing on the characterization of host immunoprotective and immunopathologic responses to infection, host-bacterium-vector interactions, and new vaccine approaches and candidates are appropriate subjects for an application.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Immune Responses to Lyme Disease Infection and Vaccination, is related to the priority areas of immunity and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and foreign non-profit and for-profit organizations and institutions, State and local governments and their agencies, are eligible to apply. Minorities and women are encouraged to apply. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) award. Applications from or involving minority institutions or women's institutions are encouraged.

MECHANISMS OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01), and the FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to this RFA may not exceed five years. The earliest anticipated award date is September 1994.

This RFA is a one-time solicitation. Future unsolicited competing-continuation applications will compete with investigator-initiated applications and be reviewed according to customary review procedures.

FUNDS AVAILABLE

The estimated minimum total funds (direct and indirect costs) available for the first year of this program will be \$1,500,000. In fiscal year 1994, the NIAID plans to fund at least six R01s and/or R29s. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

The goal of this RFA is to stimulate new and innovative programs of basic and preclinical research focused on host immune responses to Lyme disease that will lead to the development of candidate vaccines. Applications submitted in response to this RFA should focus on characterizing protective and pathologic immune responses that will guide the logical development of vaccine candidates for human use. Applications with a primary focus on the development of new animal models are not appropriate for this RFA. A separate solicitation for the development of animal models for vaccine testing is planned. Examples of research goals that are appropriate for pursuing through this RFA, include, but are not limited to:

- o The characterization of protective immune responses, including the contribution of antibodies, cytokines and cell-mediated responses.
- o The identification of B- and T-cell epitopes that play a major role in the development of protective immunity and could be considered as likely vaccine candidates.
- o The identification and characterization of cross-reacting antigens that may elicit adverse host reactions to immunization.
- o The establishment of objective criteria for distinguishing chronic Lyme disease from other disease states.
- o Delineation of the role(s) of borrelia antigen variability, molecular mimicry and persistence of bacteria or antigens in chronic Lyme disease.
- o The evaluation of candidate immunogens for the duration of active immunity, and the extent of cross-protection among borrelia strains.
- o Studies of host-bacterium or host-vector-bacterium interactions important in the establishment or prevention of infection.

These studies are all necessary prerequisites to the development of an effective vaccine that will protect human hosts from infection without risk of harmful side effects resulting from immunization.

SPECIAL REQUIREMENTS

NIAID program staff will organize annual meetings which Principal Investigators, and other key members (as designated by the Principal Investigators in consultation with the program staff) of the projects, will be asked to attend to discuss progress. This will facilitate overall program planning and development, evaluation of the feasibility of planned approaches, and will promote productive interactions among the awardees. Funds for travel to these meetings must be included in the budget. NIAID program staff will also ensure and arrange for the participation in these meetings of investigators from other relevant NIAID-supported Lyme disease research projects, if appropriate, in order to further promote relevant interactions.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 7, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number and FAX number of the Principal Investigator, the identities of other key personnel and the participating institution(s), and the number and title of the RFA in response to which the application may be submitted. A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. It will be used to assist NIAID staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The deadline for receipt of applications is March 18, 1994. Applicants for FIRST (R29) awards must attach three reference letters (in sealed envelopes) to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center of Research Resources may wish to identify the Center as a resource for conducting the proposed research. If so, a letter of agreement from the GCRC Program Director should be included in the application material.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title (Immune Responses to Lyme Disease Infection and Vaccination) and number (AI-94-008) must be typed on line 2a of the face page of the application.

The typed original, signed application package and three exact single-sided photocopies must be sent or delivered in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional exact copies must be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

Applications received after the receipt date will be returned without review. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not exclude the submission of substantial revisions of application already reviewed. These applications must, however, include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications and supporting material will be reviewed by the DRG for completeness and by the NIAID staff for responsiveness to the RFA. Incomplete and non-response applications will be returned to the applicant without further consideration or review. The NIAID will remove from further competition those applications judged to be non-competitive for award and will notify the applicant and the institutional business official. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee. A second level of review will be provided by the NIAID Council.

Review criteria for applications received in response to an RFA are generally the same as those for unsolicited applications:

- o Scientific, technical, or medical significance and originality of the proposed research.
- o Appropriateness and adequacy of the experimental approach and methodology proposed to accomplish the research.
- o Qualification and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research.
- o Availability of resources to carry out the proposed research.
- o Appropriateness of the proposed budget and duration of the project in relation to the proposed research.

AWARD CRITERIA

The anticipated date of award is September 1994. The NIAID will consider for funding all R01s and R29s rated by peer review as having significant and substantial scientific merit. Awards are subject to the availability of funds. Applications will also be rated for their responsiveness to the aims of the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Dr. Edward McSweeney
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A32
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7728
FAX: (301) 402-2508
E-mail: EM8P@NIH.GOV

Direct inquiries regarding the review of applications to:

Dr. Olivia Preble
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C20
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Mr. Todd Ball
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4835
6003 Executive Boulevard
Bethesda, MD 20892***
Telephone: (301) 496-7075

Schedule

Letter of Intent Receipt Date: February 4, 1994
Application Receipt Date: March 18, 1994
Scientific Review Date: June 15, 1994
Advisory Council Date: September 1994
Earliest Award Date: September 1994

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Sec. 301 (c), Public Law 78-410, as amended. The Catalogue of Federal Domestic Assistance Citation is Sec. 93.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.

REGIONAL RESEARCH CENTERS FOR MINORITY ORAL HEALTH: PHASE II

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: DE-94-001

P.T. 04, FF; K.W. 0715148, 0785040

National Institute of Dental Research
National Center for Research Resources

Letter of Intent Receipt Date: March 15, 1994
Application Receipt Date: September 21, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Dental Research (NIDR) and the Research Centers in Minority Institutions (RCMI) Program of the National Center for Research Resources (NCRR) invite applications for grants for Phase II of the Regional Research Centers for Minority Oral Health (RRCMOH) initiative. Receipt of a Phase I grant is not a prerequisite for submission of an application for a Phase II grant.

The objective of the RRCMOH initiative is to improve the oral health of U.S. racial and ethnic minorities, to expand the research opportunities for minority scientists by encouraging their participation in oral health research, and to develop and strengthen the biomedical and behavioral oral health research capacity of minority dental schools and RCMI eligible institutions.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting research priority areas. This RFA, Regional Research Centers for Minority Oral Health: Phase II, is related to the priority area of reducing health disparities among Americans by improving oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only minority dental schools and dental schools serving large minority populations are eligible to submit applications in response to this request. Applications from foreign institutions or those involving foreign collaborations are not eligible.

To be responsive to this RFA, an applicant institution must propose collaborative affiliations with other institutions that conform to the following organizational structures.

- o A minority dental school must propose an affiliation with one or more research intensive dental schools. In addition, this arrangement may include affiliations with one or more minority institutions. Applications proposing affiliations between minority institutions without substantive involvement of research intensive institutions are not acceptable.
- o A research intensive dental school serving a large minority population must propose an affiliation with one or more

research-intensive institutions and additionally may include an affiliation with one or more minority institutions.

o A research intensive institution may not be the applicant organization unless it serves a large minority population. In instances where a dental school that serves a large minority population also qualifies as a research-intensive institution, affiliations must still be proposed with one or more minority institutions.

MECHANISM OF SUPPORT

This RFA is a one time solicitation by the NIDR and the NCRR/RCMI, unless it is determined that there is a continuing program need. Under Phase II of the RRCMOH initiative, awards will be for up to five years using the Specialized Center (P50) mechanism. The earliest possible date for funding is September 1, 1995.

FUNDS AVAILABLE

It is anticipated that up to three, five-year awards may be made if a sufficient number of highly meritorious applications are received. Each award may not exceed \$500,000 in direct costs for research projects, pilot projects and cores for the first year. Additional support of up to \$100,000 in direct costs for the first fiscal year may be provided by the NCRR/RCMI program for RRCMOH-related faculty development activities where the applicant institution meets the basic RCMI eligibility criteria (i.e., more than 50 percent minority students and awards, M.D., D.D.S., Ph.D. or other relevant health science degrees). Award of grants pursuant to this RFA is contingent upon the availability of funds.

RESEARCH OBJECTIVES

Background

The NIDR, along with NCRR through the RCMI program, in recognizing the need to improve the oral health status of minorities relative to other groups, launched the RRCMOH initiative in September 1992. At that time, awards were made to six centers whose hallmark was collaboration between minority institutions and research intensive institutions committed to achieving the objectives of the program. The three year developmental grants were aimed at providing minority institutions with the opportunity to establish affiliations and organizational structures that could facilitate research on dental and oral health problems, particularly those of importance to minority populations.

Specifically, the long term objectives of the RRCMOH initiative are: (1) to improve the oral health of U.S. racial and ethnic minorities; (2) to enhance the research capabilities and participation of members of racial and ethnic minorities in oral health research; and (3) to develop and strengthen the oral health research infrastructure of minority dental schools, of dental schools serving large minority populations and of RCMI eligible institutions.

In initiating the RRCMOH program, the NIDR and the NCRR responded to evidence which shows that, on most measures of oral health, ethnic minorities are worse off than members of the U.S.A. majority population. The disparity in oral health between minority and other populations in the United States is highlighted in the NIDR Long-Range Research Plan for the Nineties, BROADENING THE SCOPE, a plan that calls for addressing all diseases affecting the oral cavity among all populations and at all ages. The development of the plan was aided by conceptual contributions from participants in dental and oral health research including minorities, who emphasized the need for consortia arrangements to strengthen the capacity of minority institutions to plan and conduct scientifically meritorious research and to engage in appropriate research training and career development.

Center Characteristics

Each center will be a consortium consisting of two or more institutions, as described under ELIGIBILITY REQUIREMENTS. The consortium will be structured to foster an alliance capable of addressing the objectives of the RRCMOH initiative. A director, affiliated with the applicant institution, and a co-director, affiliated with the principal collaborating institution, will be responsible for the scientific and administrative leadership of the center.

The director will be assisted by an administrative advisory committee of senior staff from the principal participating institutions. In addition, an independent scientific advisory committee consisting of consultants with appropriate research experience and accomplishments, but who are not associated with the participating institutions, will aid in the scientific review of all projects submitted in the application and proposed after initiation of the grant.

The center will consist of a series of related research projects and cores focusing on the oral health of minorities. The projects may be of a pilot nature or they may be regular research projects. Each project will involve participation by co-investigators from the collaborating institutions.

Core resources such as center development activities, administrative services, unique clinical facilities, animal facilities, biostatistical and computer services, and shared equipment will be supported.

Research Career Development and Training Opportunities

While formal research training activities cannot be supported directly by this grant mechanism, there is realization that participation in research supported by the RRCMOH program can have a significant impact on the career development of minority faculty members. In addition to the more traditional mechanisms of support for career development (i.e., K04 - research career development award; K15 - individual dentist scientist award; K16 - institutional dentist scientist award; K11 - physician scientist award) the RCMI program of the NCRR is providing funds to cover the cost of faculty development activities for eligible faculty members from minority dental schools or other RCMI eligible institutions. Minority dental school applicants may request up to \$100,000 per year for support of faculty development. Funds for faculty development will be provided by the RCMI program of the NCRR through a co-funding arrangement.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

It is the policy of NIH that applicants for NIH clinical research grants are required to include minorities and women

in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to also apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

LETTERS OF INTENT

Prospective applicants are asked to submit a letter of intent by March 15, 1994. The letter should contain a descriptive title of the proposed center, the name, address and telephone number of the center director, co-director, identifying information for other key personnel and participating institutions, and the number and title of this RFA. Although a letter of intent is neither required nor binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications by allowing NIDR staff to estimate the potential review workload and to avoid possible conflict-of-interest in the composition of the review panel.

The letter of intent is to be addressed to Dr. Mathew Kinnard at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Prospective applicants are advised to communicate with NIDR Extramural Program and Grants Management staff as early as possible in the planning stage of application preparation. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research, from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 telephone 301/594-7248, and from the NIDR Extramural Program administrator listed under INQUIRIES.

Applications must be received by September 21, 1994. If an application is received after that date, it will be returned to the applicant. Submit a signed, typewritten original of the application, including the checklist, and three signed, exact photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies must also be sent to:

H. George Hausch, Ph.D.
Extramural Program
National Institute of Dental Research
5333 Westbard Avenue, Room 519
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Applications that are incomplete, nonresponsive to this RFA, or exceed the first year budget limit of \$500,000 in direct costs will be returned to the applicant without further consideration. However, where indirect costs are assigned to a subcontract and counted as direct costs on the parent grant, the allowable direct cost maximum may be exceeded by the amount of the indirect costs assigned to the subcontract. Costs associated with subcontractual arrangements and/or faculty development activities must be clearly labeled and identified as such within the budget presentation and justification. Applications requesting support of faculty development activities may exceed the budget limit by up to \$100,000 in direct cost attributed to faculty development resources provided by the NCRR/RCMI program.

Applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific and technical merit by a special review committee convened by the NIDR Scientific Review Office. Applications may be subjected to triage by the committee to determine their scientific merit relative to other applications received in response to this RFA. The NIDR will withdraw from further competition those applications judged by triage to be noncompetitive for award and notify the applicant and institutional official. Applications judged to be competitive will undergo further scientific merit review. This review may involve an applicant interview or site visit. The second level of review will be provided by the National Advisory Dental Research Council.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues requests for the RFA, and address the LOI to:

Matthew Kinnard, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 594-7641
FAX: (301) 594-9720

Inquiries regarding fiscal matters may be directed to:

Ms. Theresa Ringler
Grants Management Officer
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

Inquiries regarding faculty development may be directed to:

Dr. Sidney A. McNairy, Jr.
Research Center in Minority Institutions Program
National Center for Research Resources
Westwood Building, Room 10A10
Bethesda, MD 20899
Telephone: (301) 594-7944

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive order 12372 or Health Systems Agency Review.

RESEARCH ON HIV INFECTION IN THE GENITOURINARY TRACT

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: DK-94-009

P.T. 34; K.W. 0715008, 0705075, 1002004, 1002008, 0706030

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Child Health and Human Development

Letter of Intent Receipt Date: March 9, 1994

Application Receipt Date: April 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Kidney, Urologic, and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the Center for Population Research of the National Institute of Child Health and Human Development (NICHD) solicit regular research (R01) and First Independent Research Support and Transition (R29) grant applications for support of studies focused on infections of the Human Immunodeficiency Viruses (HIV) and the effects of such infections on the genitourinary tract.

HEALTHY PEOPLE 2000

The PHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Effects of HIV Infections in the Genitourinary Tract, is related to the priority area of HIV infections. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit or nonprofit organizations, whether public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

Support of this program will be through the NIH grant-in-aid research project grant (R01) and FIRST (R29) awards. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under Public Health Service (PHS) grants policy as stated in the PHS Grants Policy Statement and this announcement.

This RFA is a one-time solicitation for applications for new awards. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The total requested project period for applications submitted in response to this RFA may not exceed 5 years. The earliest possible award date will be September 30, 1994.

FUNDS AVAILABLE

For FY 1994, \$500,000 will be committed by NIDDK and \$300,000 by the NICHD to fund applications submitted in response to this RFA. It is anticipated that up to 5 awards will be made. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Applicants must limit their requests to not more than \$160,000 direct costs for the initial budget period. Although this program is provided for in the financial plans of the NIDDK, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this announcement is to solicit applications to support cellular and molecular studies that focus on the effects of the HIV infection on the genitourinary tract. Such studies might include for example: tissues/fluid/secretions involving the urine, semen, bladder, urethra, prostate, testes, seminal vesicles, and epididymides. Broad areas for investigation could include the location of the HIV in such tissues and the effect(s) of the HIV infection on the cellular structure/function of these tissues. It is also of interest to study the effectiveness of pharmacological therapy on eradicating HIV infection in these tissues and to study the pathogenesis and treatment of urological disorders secondary to HIV infection. Studies that focus on the effect(s) of HIV infections on the physiology of the genitourinary tract as monitored by established clinical methodologies such as urodynamics, radiographic and sonographic technologies are encouraged. The various factors which influence the genitourinary manifestations of HIV infections need to be elucidated as well as the effects on the function(s) of the genitourinary tract as a result of the various treatment modalities for HIV.

Applications for clinical studies in urodynamics and urinary tract infections that have no relationship to HIV infection are not requested. Program project grant applications (P01) grant applications are not suited to this announcement.

SPECIAL REQUIREMENTS

Applicants who receive an award through this announcement are expected to attend a yearly meeting (convened by the NIDDK and the NICHD) of investigators to discuss progress and exchange research information. Funds to support the travel to these meetings may be included in the proposed budget.

STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study population of clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 9, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
FAX: (301) 594-7503

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) must be used in applying for these grants. The form is available from most institutional offices of sponsored research or from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892. Applications must be received by April 20, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NIDDK and NICHD staff function. If the application is not responsive to the RFA, staff will contact the applicant to determine whether it should be returned to the applicant or held until the next regular receipt date and reviewed in competition with all other applications.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDDK. Applications may be subjected to triage by an NIDDK peer review group if the number of applications is large compared to the number of awards to be made. Applications may be withdrawn from further competition when they are judged to be not competitive. The NIDDK will notify the applicant and institutional official of this action. Review criteria for this RFA are generally the same as those for unsolicited grant applications.

INQUIRIES

The RFA announced in this notice can be obtained from the staff listed below.

Ralph L. Bain, Ph.D.
Division of Kidney, Urologic, and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Suite 3A-05
Bethesda, MD 20892
Telephone: (301) 594-7556

Ms. Trude McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849 (NIDDK) and 93.864 (NICHD). Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EFFECTS OF HIV INFECTIONS ON THE KIDNEY

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: DK-94-010

P.T. 34; K.W. 0715008, 0715133, 0745025, 1002045

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: March 9, 1994

Application Receipt Date: April 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Kidney, Urologic, and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases solicits research project (R01) and FIRST (R29) grant applications for support of studies focused on infections of Human Immunodeficiency Viruses (HIV) and the effects of such infections on the kidney, on patients undergoing treatment with dialysis, and/or patients with a renal allograft.

HEALTHY PEOPLE 2000

The PHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Effects of HIV Infections in the Kidney, is related to the priority area of HIV infections. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit or nonprofit organizations, whether public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

Support of this program will be through the NIH grant-in-aid research project grant (R01) and the FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under Public Health Service (PHS) grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation for applications for new awards. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The total requested project period for applications submitted in response to this RFA may not exceed 5 years. The earliest possible award date will be July 1, 1994.

FUNDS AVAILABLE

For FY 1994, \$500,000 will be committed to fund applications submitted in response to this RFA. It is anticipated that 3 to 5 awards will be made. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Applicants must limit their requests to not more than \$160,000 direct costs for the initial budget period. Although this program is provided for in the financial plans of the NIDDK, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this announcement is to solicit applications in order to support cellular and molecular studies which focus on the effects of the HIV infection on renal structure and function. Studies that focus on the pathogenesis of the nephropathy associated with the HIV infections are especially sought. Studies that focus on the clinical course of the HIV infection in dialysis patients and/or patients who are renal transplant recipients are also encouraged.

SPECIAL REQUIREMENTS

Applicants who receive an award through this announcement are expected to attend a yearly meeting (convened by the NIDDK) of investigators to discuss progress and exchange research information. Funds to support the travel to these meetings may be included in the proposed budget.

STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study population of clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 9, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 594-7515
FAX: (301) 594-7503

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) must be used in applying for these grants. The form is available from most institutional offices of sponsored research or from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892. Applications must be received at the NIH by April 20, 1994.

For developing programs that deal with clinical populations, applicants may wish to consider utilization of General Clinical Research Center (GCRC) facilities. More information on the GCRC program is available from the National Center for Research Resources, telephone 301/594-7945.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NIDDK staff function. If the application is not responsive to the RFA, NIDDK staff will contact the applicant to determine whether it should be returned to the applicant or held until the next regular receipt date and reviewed in competition with all other applications.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDDK. Applications may be triaged by an NIDDK peer review group, if the number of applications is large compared to the number of awards to be made. Applications may be withdrawn from further competition if judged to be non-competitive. The NIDDK will notify the applicant and institutional official of this action. Review criteria for this RFA are generally the same as those for unsolicited grant applications.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The RFA can be obtained from and inquiries regarding programmatic issues should be directed to:

Ralph L. Bain, Ph.D.
Division of Kidney, Urologic, and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Suite 3A-05
Bethesda, MD 20892
Telephone: (301) 594-7556

Inquiries regarding fiscal matters should be directed to:

Ms. Trude McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PROGRESSION OF RENAL DISEASE: IgA NEPHROPATHY IN CHILDREN AND YOUNG ADULTS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: DK-94-014

P.T. 34; K.W. 0715133, 0785095, 0755030, 0705048, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: March 15, 1994

Application Receipt Date: April 12, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites investigators to submit innovative (1) basic research grant applications that could provide a critical insight into fundamental factors and/or mechanisms leading to progression of renal disease, and (2) clinical research applications for pilot studies in IgA nephropathy. The latter will assess the efficacy and safety of innovative therapeutic strategies aimed at preventing and/or controlling renal disease progression in children, adolescents, and young adults with IgA nephropathy.

HEALTHY PEOPLE 2000

The PHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications addressing the fundamental research aspects of this solicitation may be submitted by domestic [and foreign] for-profit or nonprofit organizations, whether public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government.

Applications addressing the clinical-pilot research aspect of this solicitation may be only submitted by domestic for-profit and nonprofit organizations, as described above.

Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

Support of this program will be through the NIH grant-in-aid research project (R01) and FIRST (R29) grant awards. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under Public Health Service (PHS) grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation for applications for new awards. Generally, future unsolicited competing

continuation applications, for either the fundamental research component of this solicitation or the clinical (pilot) trial aspect of this RFA will compete with all investigator-initiated applications and if R01's will be reviewed by a DRG Study Section. The total project period for applications submitted in response to this RFA, addressing either the fundamental research aspects of this solicitation, or the clinical (pilot) trial aspect of this RFA, may not exceed five years. A maximum of three years may be requested for foreign awards. The earliest possible award date will be September 30, 1994.

FUNDS AVAILABLE

For FY 1994, \$2,000,000 will be committed to fund applications submitted in response to this RFA. It is anticipated that five to six awards will be made to support applications addressing fundamental research, and three to four awards will be made to support applications addressing the clinical-pilot-aspect of this RFA. In order to help meet NIDDK goals for managing the costs of biomedical research, applications must limit their requests to not more than \$160,000 direct costs for the initial budget period. Although this program is provided for in the financial plans of the NIDDK, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This comprehensive research initiative is intended to (a) stimulate innovative fundamental research work that could provide a critical insight into fundamental factors/mechanisms leading to renal disease progression in general, and to the establishment of IgA nephropathy in particular; (b) identify and pilot test treatment intervention protocols that could result in control of renal disease progression in IgA nephropathy, in children, adolescents and young adults, once the diagnosis is made. The pilot protocols will test the safety and efficacy of innovative treatment interventions for IgA nephropathy.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

LETTER OF INTENT

Contents should include a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted. A letter of intent is not required, is not binding, and does not enter into the review of subsequent application. A letter of intent may be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 594-7515
FAX: (301) 594-7503

APPLICATION PROCEDURES

Applications must be submitted using form PHS 398 (rev. 9/91), available in the business or grants offices of most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the 9/91 revision of PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications which are complete and responsive to this RFA will be evaluated by an appropriate peer review group convened by the NIDDK in accordance with the usual NIH peer review procedure. Following review, the applications will be given a secondary review by the National Diabetes and Digestive and Kidney Diseases Advisory Council unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant or held until the next regular receipt date and reviewed by the Division of Research Grants.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. It is essential that the full text be obtained by prospective applicants before an application is developed. The full text of this RFA may be obtained from, and inquiries regarding programmatic issues should be directed to:

Gladys H. Hirschman, M.D.
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-07
Bethesda, MD 20892
Telephone: (301) 594 7584

Inquiries regarding fiscal matters should be directed to:

Aretina D. Perry
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849 for DKUHD. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TIMING OF ENVIRONMENTAL EXPOSURES IN BREAST CANCER

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: ES-94-004

P.T. 34; K.W. 0715036, 1007003

National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: March 8, 1994

Application Receipt Date: April 8, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Research on environmentally related causes of breast cancer and its prevention is a priority of the National Institute of Environmental Health Sciences (NIEHS). Accordingly, the goal of this RFA is to stimulate research on the role of environmental factors in the etiology of breast cancer. Of particular interest are aspects related to the timing of the exposures to harmful environmental agents and the subsequent cellular and genetic changes that may lead to breast cancer. Another equally important area of research is to develop a better understanding of what effects environmental agents have on the normal growth and development of mammary gland tissues. In vitro and in vivo studies that further our understanding of the influence of environmental factors on sex steroid hormones, growth factors, and receptors in cellular and genetic processes are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Timing of Environmental Exposures in Breast Cancer, is related to the priority areas of environmental health and cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone (202) 783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition Awards (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) and FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for R01 applications submitted in response to the present RFA may not exceed four years; R29 applications must be for five years.

This RFA is a one-time solicitation for applications for new awards. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for the entire program is \$1.5 million. The expected range of number of awards is five to six.

RESEARCH OBJECTIVES

This research program is designed to stimulate experimental work in three important areas to enhance our understanding of environmental influences on normal breast development and breast cancer. These are to understand the cellular and genetic effects of environmental agents on the normal growth and development of the mammary gland, to study the role of environmental factors in the development of breast cancer, and to explore the role of timing of these agents during critical developmental periods as it pertains to future risk of abnormal development and carcinogenesis. Research into how exposures during these periods effect the latency of the disease is also desirable. It should be noted that research that explores the cellular, genetic and hormonal aspects of normal and abnormal breast development, without regard to the role of environmental factors will not be considered responsive to this RFA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 8, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, identities of other key personnel and consultants, participating institutions, and number and title of the RFA to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NIEHS staff to estimate the potential review work load and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Ethel B. Jackson, D.D.S.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7826
FAX: (919) 541-2503

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Detailed instructions on submission procedures are described in the RFA. It should be noted that the National Cancer Institute has an interest in the subject matter of this RFA. Applications will be given an Institute assignment based on current referral guidelines for funding components of PHS.

REVIEW CONSIDERATIONS

Applications will be administratively reviewed by NIH staff for completeness and responsiveness to this RFA. Applications found to be incomplete or nonresponsive will be returned to the applicant without further consideration. Those applications that are complete and responsive may be subjected to triage to determine their scientific merit relative to other applications received in response to this RFA. The NIEHS will administratively withdraw from competition those applications judged to be noncompetitive and so notify the applicant and institutional official. Those applications judged to be competitive will undergo further scientific merit review by an IRG convened by the NIEHS. Applications assigned to ICDs other than NIEHS will compete for available funds with all other approved applications assigned to that ICD.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and requests for the RFA to:

Gwen W. Collman, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-4980

Direct inquiries regarding fiscal matters to:

Mr. David L. Mineo
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.113 and 93.115. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 43 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ENVIRONMENTAL EQUITY: PARTNERSHIPS FOR COMMUNICATION

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: ES-94-005

P.T. 34; K.W. 0725000, 1004017

National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: March 1, 1994

Application Receipt Date: April 1, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The purpose of this program is to strengthen the NIEHS effort that supports research aimed at achieving environmental equity for socioeconomically disadvantaged and medically underserved populations in the United States. One goal of the Institute is to stimulate investigative efforts that attempt to address questions related to the influence of economic and social factors on the health status of individuals exposed to environmental toxicants.

This component of the NIEHS environmental equity research program is designed to stimulate community outreach, training, and education efforts that will become the catalyst for reducing exposure to environmental pollutants in underserved populations. The main objective of this RFA is to establish a new paradigm for linking members of a community, who are directly affected by adverse environmental conditions, with researchers and health care providers.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, "Environmental Equity: Partnerships for Communication," is related to the priority area of Environmental Health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001- 00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and nonprofit organizations, both public and private, including predominantly minority institutions, individually or as joint efforts of minority institutions and majority institutions. It is important to note that, because of the wide range of environmental health problems to be addressed and the diversity of affected communities, applications should include at least one of each of the following in order to be considered responsive to this RFA:

- o A research scientist in environmental health sciences (such as those at NIEHS Environmental Health Sciences Centers).
- o A primary health care provider directly involved in a community affected by an environmental pollutant.
- o A member of an organization representing an underserved community affected by an environmental pollutant.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Education Grant (R25). The total project period for applications submitted in response to the present RFA may not exceed four years, and projects are not renewable.

FUNDS AVAILABLE

The estimated total funds available for the first year of support of the entire program are anticipated to be \$500,000. The maximum award will be \$150,000 in direct costs per year. It is anticipated that one to three grants will be awarded.

RESEARCH OBJECTIVES

Environmental equity refers to the perceived unequal burden of residential exposure to greater than acceptable levels of environmental pollution, occupational exposure to hazardous substances, and fewer civic benefits such as sewage and water treatment borne by socioeconomically disadvantaged persons.

The main objective of this program is to establish a new paradigm linking members of a community, who are directly affected by adverse environmental conditions, with researchers and health care providers. Development of community-based strategies to address environmental health problems requires approaches that are not typically familiar to the research and medical communities. Customary approaches to risk assessment and management often neglect the sociocultural context of environmental hazards. The distinctive needs of individual communities and their inhabitants are only rarely considered in identifying environmental health problems and devising appropriate medical intervention tactics. Underserved populations are often diverse, fragmented, and isolated, making it difficult to obtain their input and to integrate their concerns into decision-making processes. Assays of the health effects of environmental pollution, as well as regulations based on such assays, are often performed with little or no input from the affected community. The purpose of this program is to institute mechanisms to bridge this communication gap.

Applicants, therefore, are expected to create partnerships among researchers in environmental health, health care providers, and representatives of low-income or minority communities affected by environmental health problems.

The following factors should be included:

- o A means of establishing effective input from an underserved community affected by an environmental toxicant.
- o An objective assessment process designed to identify priority areas in environmental health as perceived by community members, to develop a consensus among community members as to plausible approaches, and to detect any potential constraints in implementing the project.
- o Development of appropriate education/communication modules and provision for dissemination of relevant information within the community as well as a means for the community to have a voice that reaches researchers and health care providers.
- o Feedback and evaluation of the project's effectiveness.
- o Recommendations for future activities, beyond the period of NIEHS funding, to assure continued participation of community members in research and service programs addressing environmental inequities.

Applications lacking any of the above components will not be considered.

SPECIAL REQUIREMENTS

Directors of these grants will be asked to attend an annual meeting at NIEHS.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in a study population, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1994, a letter of intent that includes a descriptive title of the proposed project, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. The letter of intent influences neither review nor funding decisions, but it is helpful to NIEHS staff in planning the review process, e.g., in estimating workload and avoiding conflict of interest.

The letter of intent is to be sent to:

Ethel B. Jackson, D.D.S.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 17-09
Research Triangle Park, NC 27709

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) must be used in applying for these grants. These forms are available at most institutional offices of sponsored research, and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7378.

Applications must be received by April 1, 1994. If an application is received after that date, it will be returned to the applicant. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application.

Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies, to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

At the time of submission, two additional copies should be sent to Dr. Ethel Jackson, NIEHS, at the above address.

REVIEW CONSIDERATIONS

Applications will be administratively reviewed for responsiveness to the RFA. Applications may be triaged on the basis of relative competitiveness. Those applications judged to be competitive will undergo further merit review. The second level of review will be provided by the National Advisory Environmental Health Sciences Council.

Potential applicants are strongly encouraged to consider carefully the specific review criteria listed in the RFA before submitting an application or contacting staff.

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Donald McRee, Ph.D.
Environmental Health Resources Branch
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
P.O. Box 12233, MD 3-02
Research Triangle Park, NC 27709
Telephone: (919) 541-7634

Direct inquiries regarding fiscal matters to:

Mr. David Mineo
Grants Management Branch
National Institute of Environmental Health Sciences
Division of Extramural Research and Training
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7628

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.113, 93.114 and 93.115. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 100-607) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. The program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PREDOCTORAL FELLOWSHIP AWARDS FOR MINORITY STUDENTS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: GM-94-004

P.T. 22, FF; K.W. 0720005

National Institute of General Medical Sciences

Application Receipt Date: April 27, 1994

PURPOSE

The National Institute of General Medical Sciences (NIGMS) is accepting applications for individual National Research Service Award (NRSA) Predoctoral Fellowships for Minority Students. These fellowships will provide up to five years of support for research training leading to either the Ph.D. degree or the combined M.D./Ph.D. or other combined professional doctorate/research Ph.D. degrees in the biomedical sciences for highly qualified students from minority groups found to be underrepresented in the biomedical and behavioral sciences. Support is not available for individuals enrolled in medical or other professional schools unless they are enrolled in a combined professional doctorate/Ph.D. degree program in biomedical research.

The intent of this Minority Predoctoral Fellowship Program is to make graduate fellowships available to underrepresented minority graduates from all institutions, including the many minority undergraduate students who have participated in the various NIH-sponsored programs to prepare them for research careers. This program is designed to encourage greater numbers of underrepresented minorities to pursue graduate degrees, thus fulfilling the goal of increasing the number of minorities trained for careers in biomedical research.

ELIGIBILITY REQUIREMENTS

Eligibility for these awards is limited to students who are U.S. citizens, non-citizen nationals (citizens of areas outside the U.S., but under U.S. jurisdiction), or permanent U.S. residents. Applicants must be from ethnic/racial groups that are underrepresented in research in the biomedical sciences in the U.S. For purposes of this announcement, underrepresented minority students are defined as individuals belonging to a particular ethnic or racial group that has been determined by the applicant's graduate institution to be underrepresented in biomedical or behavioral research. In making these awards, the NIH will give priority consideration to applications from Blacks, Hispanics, Native Americans, and Pacific Islanders and other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research nationally.

In addition, an applicant must currently be enrolled in a Ph.D. or combined M.D./Ph.D. (or other combined professional doctorate/research Ph.D. graduate) program in the biomedical sciences, or have been accepted by and agreed to enroll in such a graduate program in the 1994-95 academic year.

The Minority Access to Research Careers (MARC) Program of NIGMS has a similar fellowship program of support for graduates of its various MARC Honors Undergraduate Research Training programs to attend graduate school in biomedical sciences. Graduates of the MARC Program are encouraged to apply to the MARC Predoctoral Fellowship Program.

MECHANISM OF SUPPORT

This RFA for individual fellowships (F31) is under the auspices of the NRSA Act. An applicant must work with her/his research advisor or graduate program director in preparing the application. Awards will be administered under the PHS Grants Policy Statement and the Guidelines for National Research Service Awards and as stated in this RFA.

The period of fellowship support requested in response to this RFA may not exceed five years (Note: the total period of predoctoral training grant support under the NRSA authorization may not exceed five years). Continuation of the fellowship award for each subsequent year beyond the first is based on evidence of satisfactory progress in a graduate program.

There is a single receipt date for applications: April 27, 1994. The NIGMS may announce subsequent RFA receipt dates at a later time.

Stipends and Other Expenses

The fellowship award provides an annual stipend to help meet the fellow's living expenses; a tuition and fee allowance in accordance with NIH policy; and an annual institutional allowance of \$2000, which may be used for travel to scientific meetings and for laboratory and other training expenses.

FUNDS AVAILABLE

For FY 1994, it is anticipated that at least 50 new fellowship awards will be made, if sufficient numbers of high quality applications are received. The NIGMS will be joined by the following awarding components of the NIH in providing funds to support this program: National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Cancer Institute, National Institute of Child Health and Human Development, National Institute on Deafness and Other Communicative Disorders, National Institute of Dental Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute on Drug Abuse, National Institute on Environmental Health Sciences, National Eye Institute, National Heart, Lung and Blood Institute, National Institute of Mental Health, National Institute of Neurological Disorders and Stroke, National Library of Medicine, National Center for Human Genome Research, and National Center for Research Resources. Although this program is included in the financial plans of the participating institutes and centers, the award of fellowships in response to this RFA is also contingent upon the availability of funds for this purpose.

Payback Requirements

The NIH Revitalization Act of 1993, signed into law on June 10, 1993, includes provisions in Section 1602, which eliminate the payback obligation requirements for predoctoral support. Accordingly, Section VII (pages 29 and 30) of the fellowship application, PHS 416-1, Revised 10/91, are no longer applicable to this program. For more details concerning this change, see the NIH Guide for Grants and Contracts, Volume 22, Number 27, July 30, 1993.

APPLICATION PROCEDURES

The fellowship application form PHS 416-1 (rev. 10/91) is to be used in applying for these grants. These forms are available at most university offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NIH program administrators listed under INQUIRIES.

The applicant must follow ALL instructions in the application kit AND those described in these supplemental instructions. Incomplete applications will not be reviewed.

The following must be included with the application at the time of submission. Failure to include any of these items will preclude review of the application.

- o a copy of the results of either the Graduate Record Examination or the Medical College Admission Test (for M.D./Ph.D. applicants);
- o a clear and legible copy of the applicant's transcript(s) from all undergraduate and graduate institutions in which the applicant is/has been enrolled;
- o a description of the graduate or combined degree program in which the applicant is either enrolled or has been admitted and agreed to enroll (Item 33);
- o at least three reference letters sealed in envelopes; and
- o certification of eligibility completed by the institution.

Supplemental Instructions for Completing the Application

A. To be completed by the Student-Applclicant

Item 1. ("Title of Research Training Proposal"), type: MINORITY PREDOCTORAL FELLOWSHIP PROGRAM - NIGMS.

Item 2. ("Level of Fellowship") type: Predoctoral.

Item 3. ("Program Announcement Area"), type: RFA GM-94- 004.

Items 4-8. Self explanatory.

ITEM 4i ("Citizenship"), see explanation on page 7 of PHS 416-1. Non-citizen nationals are citizens of areas that are not States but are under the jurisdiction of the United States, e.g., American Samoa. Applications from permanent residents MUST be accompanied by a notarized statement.

(Items 9-14. Completed by sponsor).

Item 15. YOU MUST SIGN THE APPLICATION.

Items 16-18. Self explanatory; if any do not apply to you, type N/A.

(Items 19 and 20. Completed by sponsor)

Item 21. (Abstract of Proposed Research) If you have selected a thesis topic, you should briefly describe, in abstract form, the question you are studying, how you are approaching it, and the health relatedness of your project. If you have not yet selected a thesis project, say "no thesis selected" and instead give a brief description of the research area that interests you most and why, even if your research interests are still very broad.

Item 22. (Scholastic Performance) You must complete this section, listing all undergraduate and graduate course you have taken and the grades you received. In addition, you MUST submit a LEGIBLE copy of a transcript from all undergraduate and graduate institutions you have attended.

Item 23. (Employment) In addition to prior or current NRSA support, include your employment history during and after college if a significant time commitment was involved. All time between graduation from college and entrance into this graduate program should be accounted for.

Items 24-26. Self-explanatory

Item 27. Research Experience

a. (Summary) Provide a thorough description of your relevant work and research experiences, including time, place, research director, and your role in the research.

b. (Doctoral Dissertation) should not be completed.

c. (Publications) Include a list of publications, abstracts, and poster presentations. Three (3) collated sets of copies of publications may be provided as part of Section 3 (Appendix).

Item 28. (Revised Application) To be completed ONLY if this application is a revision of an application submitted earlier.

Item 29. (Research Training Plan)

a. (Activities Under Award) - Include a statement concerning your research training and long-range career goals, with an explanation of how the proposed course of study to be supported by this fellowship will help you attain these goals. If appropriate, explain how prior work and research experiences affected the choice of career goals.

b and c. (Research Proposal and Respective Contributions) If you have selected a research thesis topic, complete this section according to the instructions. If you have not yet selected a thesis, give a description of the research area that interests you most.

d. (Selection of a Sponsor and Institution) Explain why you chose to enroll in this university/institution and in this graduate program. If you have selected a research advisor, give the rationale for your choice. If you have not selected an advisor, you should identify up to five individuals with whom you would like to work, giving a rationale for your choices.

B. To be completed by the Research Advisor or Sponsor

If the applicant has selected a research advisor, the advisor must complete the items in this section.

If the applicant HAS NOT YET SELECTED A RESEARCH ADVISOR, the director of the graduate program should designate a sponsor to complete these items. The director may choose to serve as the sponsor.

Items 9-14, 20, and 30-37

Item 33, in addition to the information requested in the application kit,

(1) for ALL students, provide a full description of the graduate or combined degree program in which the applicant is (or is to be) enrolled. This description should also outline the normal course of study (both didactic and laboratory) for students enrolled in the program;

(2) for students ALREADY ENROLLED in the graduate program, describe the applicant's course of study up to the time of submission of the application and plans for further study; and

(3) for ALL students, provide the applicable tuition and fees for each year of support requested.

C. To be supplied by the University or Institution

1. A statement from the institution certifying that (a) the applicant is enrolled as a predoctoral student OR has been accepted by and agreed to enroll in the graduate training program; (b) the applicant is an eligible minority individual, determined by the institution to be underrepresented in biomedical or behavioral research; this certification MAY include an OPTIONAL identification of the applicant's ethnic/racial group; and (c) the applicant is a citizen, non-citizen national or permanent resident of the U.S. (see page 7 of PHS 416-1, Rev. 10/91). This statement must be signed by the director of the graduate program in which the student is (or is to be) enrolled and by the official authorized to sign for the institution. FAILURE TO INCLUDE THIS CERTIFICATION WILL PRECLUDE REVIEW OF THE APPLICATION. The institution may wish to use the format given at the end of this announcement.

2. By signing item 37, the institution is certifying the accuracy of the tuition and fees requested for each year of support listed in Item 33.

Submission

Submit a signed, typewritten original of the application (including the Checklist, Personal Data form, at least three sealed reference letters, and all other required materials) and two exact, clear, single-sided photocopies of the signed application, in one package to:

Division of Research Grants
National Institute of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications must be received by April 27, 1994. Any application received after that date will be returned to the applicant.

Applications submitted without three reference letters will be returned without review.

Simultaneous submission of identical applications will not be allowed nor will essentially identical applications be reviewed by different review committees. Thus, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique. If a candidate submits an application in response to this RFA that is substantially similar to one s/he has already submitted to the NIH for review but which has not yet been reviewed, the applicant will be asked to withdraw one of them.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness to this announcement. Incomplete or non-responsive applications will be returned to the applicant without review. All items listed above (see APPLICATION PROCEDURES) MUST be included for the application to be considered complete.

Applications may be subjected to preliminary review to determine their merit relative to other applications received in response to this RFA. The NIH will administratively withdraw from competition those applications judged to be noncompetitive and notify the applicant of such withdrawal. Complete and responsive applications that are judged to be competitive will be evaluated for scientific merit and training potential by an appropriately constituted initial review group within the NIGMS using the criteria stated below. The second level of review will be provided by the NIGMS Fellowship Overview Group.

The review criteria include:

- o academic record and research experience of the applicant;
- o quality of the graduate program in which the applicant is already enrolled or plans to enroll;
- o qualifications and research/research training experience of the applicant's sponsor or researcher advisor; the match between the research interests of the student and the research advisor/sponsor;
- o for advanced graduate students, scientific significance, originality and feasibility of proposed research; for beginning students, quality and clarity of stated research interests.

AWARD CRITERIA

The anticipated date of award is September 30, 1994. Award decisions will be based on the technical merit of the applications based on the review criteria, programmatic priorities, and availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA may be directed to:

Dr. Irene Eckstrand
National Institute of General Medical Sciences
Westwood Building, Room 918
Bethesda, MD 20892
Telephone: (301) 594-7762

Dr. John Norvell
National Institute of General Medical Sciences
Westwood Building, Room 907
Bethesda, MD 20892
Telephone: (301) 594-7784

Inquiries regarding fiscal and administrative matters may be directed to:

Ms. Toni Holland
National Institute of General Medical Sciences
Westwood Building, Room 935
Bethesda, MD 20892
Telephone: (301) 594-7820

AUTHORITY AND REGULATIONS

Awards are authorized by sections 301 and 405 of the Public Health Service Act, as amended and administered under PHS grants policies and Federal Regulations 45 CFR Part 74 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. This program is described in the Catalog of Federal Domestic Assistance No. 93.960, Special Minority Initiatives Program.

PERINATAL EMPHASIS RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: HD-94-013

P.T. 04; K.W. 0755013, 0710030, 0403020, 0775020

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: February 7, 1994
Application Receipt Date: May 24, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites applications from current members of the Perinatal Emphasis Research Centers (PERC) program (competitive continuation applications) and from prospective members (new applications) with the objective of encouraging investigators to develop multidisciplinary research efforts that will advance knowledge about diseases and disorders of pregnancy and infancy and about special issues relevant to rural populations. These grants are for the support of hypothesis-testing research efforts; they are not intended to support service or demonstration projects. PERCs are organized around problem/need themes and are established where research can be coordinated with existing programs of health care to ensure the rapid assimilation of new scientific knowledge into health care delivery. Active PERCs are addressing issues in high-risk pregnancies (diabetes, hypertension), prevention of prematurity, fetal hypoxia, intrauterine growth retardation, and infant sleep physiology.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Perinatal Emphasis Research Centers, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applications may be submitted by domestic organizations, public and private, such as universities, colleges, hospitals, and laboratories. Applications from investigators who are minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA solicits applications that will be awarded as NIH Specialized Research Center Grant (P50). The duration of these award is for five years. They must have at least three projects at all times, and have core(s) serving as a resource for at least three projects at all times. It is expected that up to two awards will be made as the result of this RFA (one award in the area of perinatology and one in the area of rural maternal-infant health).

FUNDS AVAILABLE

It is anticipated that two center grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds. To fund these awards, \$1,200,000 has been set aside for the direct costs in the first year.

RESEARCH OBJECTIVES

A major goal of the PERC program is to develop new knowledge about diseases and disorders of pregnancy and infancy with the aim of reducing infant morbidity and mortality.

A PERC grant is used to promote and support multidisciplinary research efforts in areas where (a) knowledge gaps are not being sufficiently addressed by ongoing research, or (b) there are needs to stimulate and intensify efforts in promising research areas. Through the PERC programs for mothers and infants, NICHD has undertaken concerted biomedical and behavioral research efforts directed toward improving pregnancy outcome and ensuring infant survival and well-being. PERCs are located throughout the United States.

Research concerns include, but are not necessarily limited to, the following:

1. High-Risk Pregnancies (e.g., diabetes, hypertension, drug abuse) - Effects upon pregnancy, fetal development, and neonatal adaptation.
2. Intrauterine Growth - All aspects that may contribute to the regulation of fetal growth such as role of growth factors, hypoxia, nutrients, hormones, infections; placental function; regulation of maternal blood volume and uterine and umbilical blood flow; methodology to assess fetal health and development.
3. Perinatal Toxicology and Pharmacology - Effects of drug administration to the mother or fetus on gestation and pregnancy outcome; neonatal toxicology and pharmacology; drug distribution in tissues; role of nutrition, stage of pregnancy, placental function, and maternal or fetal disease; interplay of genetic composition and environment; drug action during perinatal period on both mother and/or fetus and newborn infant.
4. Initiation of Labor - Normal and abnormal mechanisms and outcomes in term, preterm, and/or postterm births.
5. Neonatal Disorders - Adaptation, response to external stimuli, unique nutritional requirements, response to acute and chronic injury (including asphyxia, ROP, BPD, NEC), remodeling and repair, immune function and development.
6. Perinatal epidemiology and clinical research addressing the special needs of rural populations. Overall goals are similar to the ones stated above; developing and testing interventions to reduce infant mortality, low birth weight, intrauterine growth retardation, and preterm delivery as they apply to stable and statewide rural populations.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 7, 1994, a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the Principal Investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NICHD staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Charlotte Catz at the address listed under INQUIRIES.

APPLICATION REQUIREMENTS

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of an application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box checked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Susan Streufert, Ph.D.
Division of Scientific Review
National Institute of Child Health and Human Development
Building 6100E, Room 5E03F
Bethesda, MD 20892
Telephone: (301) 496-1485

REVIEW CONSIDERATIONS

Applications will be received by the Division of Research Grants and reviewed for completeness. Incomplete applications will be returned to the applicant. NICHD staff will review the applications for responsiveness to the RFA. Applications judged to be nonresponsive will be returned. Responsive applications may be subjected to a triage by a peer-review group to determine the scientific merit relative to the other applications received in response to this RFA. The NICHD will withdraw from competition those applications judged to be non-competitive and will notify the applicant and institutional official. Those applications judged to be competitive will be further evaluated for scientific and technical merit by a review group convened solely for this purpose by the Division of Scientific Review, NICHD. Following review by the Initial Review Group, applications will be evaluated by the National Advisory Child Health and Human Development Council for program relevance and policy issues before awards for meritorious applications made.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Charlotte Catz
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Building 6100E, Room 4B03E
Bethesda, MD 20892
Telephone: (301) 496-5575
FAX: (301) 402-2085

Direct inquiries regarding fiscal matters to:

Mr. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100E, Room 8A17F
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

These programs are described in the Catalog of Federal Domestic Assistance under number 13.965, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Sections 1004, 301 and 444, and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to A-95 Clearinghouse or Health Systems Agency Review.

MOLECULAR BIOLOGY: RESOURCE DATABASE SUPPORT

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: LM-94-001

P.T. 34; K.W. 1002008, 1004017, 0780018

National Library of Medicine

Letter of Intent Receipt Date: February 15, 1994
Application Receipt Date: March 29, 1994

PURPOSE

The National Library of Medicine (NLM) announces the availability of a Request for Applications (RFA) to support the maintenance of protein databases in the field of molecular biology. Sources of data will be from the published literature or other databases, and may contain sequence data, NMR structural data, or other types of data useful to molecular and protein biologists. When data is derived from the published literature, the record will contain full bibliographic citation information.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Molecular Biology: Resource Database Support, is related to the priority area of preventive services particularly as related to genetic disease. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy Report: (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. However, domestic applications may include international components. Applications from minority individuals and women are encouraged. Although an application must be submitted from a single institution, it may include consortia arrangements with other institutions provided these arrangements

are clearly delineated and confirmed by signed statements from the responsible officials of each institution.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) biotechnology resource grant (P41). Activities to be supported under this grant are limited to the maintenance and management of the database and to making it available to other researchers. Any research related to these activities must be submitted separately as an individual research grant (R01) application, which would compete with other R01 applications. Research in database management is not a part of this RFA. The total project period for applications submitted in response to this RFA may not exceed five years. The anticipated award date is August 1994. This RFA is a one-time solicitation.

FUNDS AVAILABLE

Although financial plans for fiscal year 1994 include \$1.5 million for this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that up to three grants will be awarded under this program. The specific amount to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds.

RESEARCH OBJECTIVES

The primary goal of this initiative is provide support to assist and enhance existing public information resources for biotechnology, in particular--protein sequence databases, NMR databases, and other related research information resources. Examples include correcting taxonomy, nomenclature, additional protein features, and mutation information. The input for such databases may arise from the published literature, data generated in the applicants laboratory, or be submitted from other sources. Access to the database may be online, CD ROM or other. The existence of the database and how to access it must be clearly disseminated. End-user software development, research, and training (other than a tutorial on the database) are not a part of this initiative. It is expected that an external advisory committee will be formed to provide consultation to the grantee.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 15, 1994, a letter of intent that includes a descriptive title of the database, the name, address, and telephone number of the project director, the identities of other key personnel and participating institution(s), and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful to the NLM staff in planning for the timely review of applications. It allows NLM staff to estimate the potential workload and to avoid possible conflict of interest in review. The letter of intent is to be addressed to Dr. Roger W. Dahlen at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). These forms are available at most institutional office of sponsored research; from the Office of Grant Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NLM Program Director listed under INQUIRIES.

The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to Dr. Roger W. Dahlen at the address listed under INQUIRIES.

Applications must be received by March 29, 1994. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness and responsiveness to the objectives or the RFA. Incomplete applications will be returned to the applicant without further consideration. If an application is judged to be not responsive, the applicant will be contacted to withdraw the application or have it considered as an unsolicited application in the next review cycle.

Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group, convened by the Division of Extramural Programs, NLM, solely to review these applications. This initial review may include a preliminary evaluation to determine scientific and technical merit relative to the other applications received in response to the RFA (triage); the NIH will withdraw from further consideration applications judged to be noncompetitive and promptly notify the project director and the official signing for the applicant organization. Those

applications judged to be competitive will be further evaluated for scientific/technical merit by the usual peer review procedures. The second level review will be by the Board of Regents of the National Library of Medicine.

The proposed resource database is expected to be highly responsive to a national user community. It is the applicant's responsibility to identify user community(s) that both need and will use the capabilities to be provided by the resource. The reviewers will evaluate:

- o Scientific merit and feasibility;
- o The impact and relevance of the resource database on the user community(s) it will serve;
- o The estimated annual use of the resource by scientists and the potential idle or down time;
- o The reasonableness and duration of the proposed budget;
- o The significance, promulgation and adoption elsewhere of new discoveries made from use of this resource;
- o Likelihood that utilization of the resource will lead to new applications of the resource's technology in biomedical research and thereby to expanded use of the resource;
- o The institution's commitment to the resource: for example, costs associated with alterations and renovations, purchase of routine equipment and salaries of some resource staff may be borne by the applicant institution;
- o The scientific and managerial credentials of the Principal Investigator and the other professional staff; and
- o Quality and appropriateness of management and administrative arrangements;
- o Plans for an advisory committee, and whether the members have or will have sufficient breadth and ability to take an effective role in the review and guidance of the resource operations;

AWARD CRITERIA

Applicants should be aware that, in addition to scientific and technical merit, program priorities and program balance, the total cost of the Resource Database to the NLM will be considered by NLM staff and the Board of Regents in making funding recommendations.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and address the letter of intent to:

Dr. Roger W. Dahlen
Extramural Programs
National Library of Medicine
Bethesda, MD 20894
Telephone: 301-496-4221

Direct inquiries regarding fiscal and administrative matters to:

Mr. Brian Campbell
Extramural Programs
National Library of Medicine
Bethesda, MD 20894
Telephone: 301-496-4253

AUTHORITY AND REGULATIONS

The programs of the Division of Extramural Programs, NLM, are described in the catalog of Federal Domestic Assistance Number 93.879. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) and administered under PHS grants policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency review.

SYMPTOM MANAGEMENT: ACUTE PAIN

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: NR-94-003

P.T. 34; K.W. 0715150, 0785130, 0745027, 0710030

National Institute of Nursing Research

Letter of Intent Receipt Date: March 15, 1994

Application Receipt Date: April 21, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION,

FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The focus of this RFA is on interventions to improve the assessment, management, and prevention of acute pain. Studies that address the multidimensional nature of pain, which includes a range of physiological, sensory, affective, behavioral, cognitive, and sociocultural factors, are encouraged in order to provide a scientific basis for clinical practice.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), "Symptom Management: Acute Pain," is related to the priority areas of cancer and other disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783- 3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (October 1, 1990). The total project period for applications submitted in response to the present RFA may not exceed three years. The anticipated award date is September 30, 1994. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also, but will generally be in the range of \$150,000 to \$180,000 direct costs. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$1,200,000 in total costs for the first year will be committed to fund applications submitted in response to this RFA. It is anticipated that four to six applications will be funded.

RESEARCH OBJECTIVES

The NINR is interested in innovative studies relevant to the assessment, management, and prevention of acute pain and exacerbations of acute pain associated with chronic conditions such as cancer, arthritis, and sickle cell anemia. Studies may address issues relating to pharmacological and nonpharmacological interventions, although studies addressing drug development and testing for pain relief are not acceptable. Investigations of prevention regimens are needed, particularly for surgical and cancer patients.

Applications are invited for the support of projects that address issues including, but not limited to:

- o testing appropriateness and adequacy of pharmacologic regimens for pain, including their impact on the dimensions of pain and the relationship to adjunctive non-pharmacologic approaches;
- o evaluating the effectiveness of pain practice guidelines, including measures to prevent pain;
- o examining the link between biological indicators of pain and behavioral and self-report responses as part of an intervention study;
- o testing culturally sensitive approaches to pain assessment and management;
- o investigating the effects of combined non-pharmacological and pharmacological interventions in infants, children, older persons, or the cognitively impaired;

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit by March 15, 1994, a letter of intent that includes a descriptive title, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NINR staff to estimate the potential review workload and to avoid

conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Ernest Marquez
Office of Review
National Institute of Nursing Research
Westwood Building, Room 740
Bethesda, MD 20892
Telephone: (301) 594-7865
FAX: (301) 594-7894

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). Application kits are available from most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The RFA label available in the application form PHS 398 must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA and the NRCC guidelines.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NINR in accordance with the usual NIH peer review procedures. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant. Applications may be triaged by an NINR peer review group on the basis of relative competitiveness. Those applications judged to be non-competitive for award will be withdrawn and the applicant notified. Those applications judged to be competitive will undergo further scientific merit review. The review criteria are set forth in the RFA. Questions concerning the responsiveness of proposed research to the RFA may be directed to program staff listed under INQUIRIES. The second level of review will be provided by the National Advisory Council for Nursing Research.

INQUIRIES

Phone requests for the RFA and NRCC Guidelines may be made to Ms. Anissa Nash
NINR, Publication, (301)496-0207.

Written and telephone inquiries concerning the objectives and scope of this RFA. Direct written requests for the RFA and all inquiries regarding programmatic issues to:

Mary D. Lucas, Ph.D., R.N.
Acute and Chronic Illness Branch
National Institute of Nursing Research
Westwood Building, Room 752
Bethesda, MD 20892
Telephone: (301) 594-7397

For administrative and fiscal matters contact:

Sally A. Nichols
National Institute of Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 594-7498

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.361 Nursing Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Health Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EXTRAMURAL RESEARCH FACILITIES CONSTRUCTION PROJECTS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

RFA AVAILABLE: RR-94-003

P.T. 02; K.W. 0710030

National Center for Research Resources

Letter of Intent Receipt Date: February 18, 1994
Application Receipt Date: April 8, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Center for Research Resources is authorized under Sections 481A and 481B of the Public Health Service Act, as amended by the National Institutes of Health Revitalization Act, Public Law (PL) 103-43, to "make grants to public and nonprofit private entities to expand, remodel, renovate or alter existing research facilities or construct new research facilities" for biomedical and behavioral research and research training.

The Appropriations Act for the Department of Health and Human Services for Fiscal Year 1994 (PL 103-112) provides \$7,000,000 in the budget of the National Center for Research Resources (NCRR) of the National Institutes of Health (NIH) for extramural facilities construction grants, to be awarded competitively. The NCRR is issuing a Request for Applications (RFA) RR-94-003 for support of construction and renovation of facilities for biomedical and behavioral research and research training.

Applications for construction grants that were submitted previously to the NIH must recompute under this RFA.

ELIGIBILITY REQUIREMENTS

Under Section 481A of the Public Health Service (PHS) Act, domestic, non-Federal, public and private non-profit institutions, organizations, and associations that conduct or support biomedical/behavioral research are eligible to apply. An institution of emerging excellence must have been so designated under Section 739 of the PHS Act as revised in PL 102-408, and received a PHS Centers of Excellence grant award in Fiscal Year 1993 to be eligible to apply. Under Section 481B of the PHS Act, Regional Primate Research Centers are also eligible to apply.

In addition to any applications from Regional Primate Research Centers or recipients of 1993 PHS Centers of Excellence awards an institution may submit only one application in response to this specific announcement. For example, a medical school and a dental school of the same institution, even if separated geographically, may not submit separate applications.

MECHANISM OF SUPPORT

The award mechanism will be the construction grant award (C06). Awards will be administered under Federal Regulation 45 CFR Part 74 - Administration of Grants. Matching funds from non-Federal sources will be required.

FUNDS AVAILABLE

This one-time solicitation is based on the Fiscal Year 1994 appropriation that provides \$7,000,000 for this initiative, with up to 25 percent of these funds targeted for institutions of emerging excellence. Up to 50 percent of the necessary and allowable costs of a project may be awarded, or 40 percent of costs proportionate to use in a multipurpose facility, not to exceed \$2,000,000. Because the nature and scope of the activities proposed in response to this RFA may vary, it is anticipated that four to ten awards at different levels will be made. Prior to grant award, the applicant must provide an assurance of required matching funds and that additional funds will be secured to meet any projected costs in excess of the award amount. Requests of less than \$500,000 will not be accepted. No indirect costs or continuation costs will be awarded.

LETTER OF INTENT

Prospective applicants are asked to submit by February 18, 1994, a letter of intent to the individual noted below. The letter, requested for planning purposes only, should identify the RFA number noted above, the Principal Investigator, and include a brief title of the type(s) of research or research support to be conducted in the new facility. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIH staff to estimate the potential workload and to avoid conflict of interest in the review. The letter of intent is to be addressed to:

Dr. Charles L. Coulter
Research Facilities Improvement Program
National Center for Research Resources
Westwood Building, Room 8A15
Bethesda, MD 20892
Telephone: (301) 594-7952

APPLICATION PROCEDURES

Applicants must use Standard Form 424, "Application for Federal Assistance." Application forms and special instructions for completing the forms relevant to this RFA must be requested from the staff contact official noted below.

REVIEW CONSIDERATIONS

Applications will be reviewed by DRG staff for completeness and by NCRR staff to determine administrative and programmatic responsiveness to this RFA. Those judged to be incomplete or nonresponsive will be returned to the applicant without review. Those considered complete and responsive may be subjected to a triage review to determine their scientific merit relative to the other applications submitted in response to this RFA. This triage review will be done by the Biomedical and Behavioral Research Review Committee or a subgroup thereof, established for the purpose of initial peer review by the NCRR.

The NIH will withdraw from competition those applications judged by the triage peer review group to be noncompetitive for award and will so notify the applicant investigator and the institutional business official. Those applications judged to be competitive for award will be reviewed for scientific and technical merit by the Biomedical and Behavioral Research Review Committee to be convened by the Office of Review, NCRR. The second level of review will be provided by the National Advisory Research Resources Council in September 1994.

AWARD CRITERIA

Factors considered in making awards include the merit of the application, the needs of the institution (with special consideration for institutions designated as institutions of emerging excellence), the commitment of the institution, the availability of funds, and the overall program priorities. Awards will be made on or before September 30, 1994.

INQUIRIES

Inquiries for further information or clarification regarding this RFA are encouraged.

To request the RFA and for information concerning programmatic issues, please contact:

Dr. Charles L. Coulter
Research Facilities Improvement Program
National Center for Research Resources
Westwood Building, Room 8A15
Bethesda, MD 20892
Telephone: (301) 594-7952

For application Standard Form 424, special application instructions, and information on fiscal matters contact:

Ms. Katherine A. Springmann
Office of Grants and Contract Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

All awards will be made under the authority of the Public Health Service Act and administered under the PHS grant policies as outlined in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000 (Rev.) Department of Health and Human Services, OASH, October 1, 1990, and Federal Regulation 45 CFR Part 74. Applicants are required to comply with Executive Order 12372 as supplemented by DHHS 45 CFR Part 100, Intergovernmental Review of Health and Human Services Programs and Activities. This program will be described in the Catalog of Federal Domestic Assistance, number pending.

ONGOING PROGRAM ANNOUNCEMENTS

ACADEMIC RESEARCH ENHANCEMENT AWARD

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PA-94-022

P.T. 34; K.W. 1014006

National Institutes of Health

Application Receipt Date: June 22, 1994

PURPOSE

The National Institutes of Health (NIH) is making a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of the Nation's research scientists, but historically have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, the Academic Research Enhancement Award (AREA) program.

The AREA funds are intended to support new research projects or expand ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences. Applications received in June 1993 for AREA grants to be awarded this year (FY 1994) have been reviewed for scientific merit and program relevance. Approximately \$13.2 million will be available for the NIH AREA program in FY 1994. As a result, about 130 AREA grants will be made from the applications received June 1993. Since it is anticipated that additional funds will be available next year, the NIH is inviting grant applications at this time for AREA grants to be awarded competitively in FY 1995.

ELIGIBILITY REQUIREMENTS

Applicant Institutions

o All domestic health professional schools and other academic institutions offering baccalaureate or advanced degrees in the sciences related to health are eligible, EXCEPT those that have received research grants and/or cooperative agreements from the NIH totaling more than \$2 million per year (direct and indirect costs) in each of four or more years during the period from FY 1987 through FY 1993.

o For purposes of eligibility for the AREA program, "research grants and cooperative agreements" include the following activity codes ONLY:

K01, K02, K04, K05, K06, K08, K11, K12, K14, K15, K16, K20, K21, P01, P40, P41, P42, P50, P60, R01, R03, R10, R21, R22, R23, R24, R29, R35, R37, R55, U01, U10, U24, U41, U42, and U54.

o "Health professional schools" (schools of medicine, dentistry, osteopathy, pharmacy, nursing, veterinary medicine, public health, optometry, allied health, and podiatry) means an accredited public or non-profit private school in a State that provides training leading to a degree granted by that school, for example, a doctor of medicine, a doctor of dentistry, or equivalent degree. The term "accredited" means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education.

o "Other academic institutions" means, as a SINGLE eligible component, all other schools, departments, colleges and free-standing institutes of the institution, EXCEPT the health professional schools.

o Several applications proposing different research projects may be submitted by an applicant institution.

Proposed Principal Investigators

o Must not have active research grant support at the time of award of an AREA grant.

o May not submit a regular NIH research grant application for essentially the same project as a pending AREA application.

o Are expected to conduct the majority of their research at their own institution, although limited access to special facilities or equipment at another institution is permitted.

o May not be awarded more than one AREA grant at a time nor be awarded a second AREA grant to continue the research initiated under the first AREA grant.

APPLICATION PROCEDURES

Applications for the AREA program will be accepted under the application submission procedures of the Division of Research Grants (DRG), NIH. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for an AREA grant.

Applicants must obtain the AREA Program Guidelines containing supplemental instructions for AREA applications from the Grants Information Office, DRG, NIH (see address below). These instructions must be followed in preparing an application.

AREA grants are awarded on a competitive basis. Applicants may request support for up to \$75,000 for direct costs (plus applicable indirect costs) for a period not to exceed 36 months.

No more than \$35,000 may be requested for direct costs for any one year. Although this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies, pilot studies, and other small-scale research projects preparatory to seeking more substantial funding from the NIH research grant programs.

REVIEW CONSIDERATIONS

Applications for the AREA program will be subjected to the standard peer review process involving two sequential levels of review. The first level of review is performed by initial review groups composed primarily of non-Federal scientists selected for their competence in particular scientific fields. The second level of review is made by the National Advisory Council or Board of the NIH awarding component to which the grant application has been assigned by the DRG for potential funding. These groups are composed of both scientific and lay representatives who are chosen for their expertise, interest, or activity in matters related to the mission of the individual awarding component. Council or Board recommendations are based on both scientific merit and relevance to awarding component program goals. In general, the NIH may award a grant only if the corresponding application has been recommended for funding by both levels of review.

AWARD CRITERIA

Funding decisions will be based on the proposed research project's scientific merit and relevance to NIH programs and the institution's contribution to the undergraduate preparation of doctoral-level health professionals. Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who have obtained academic or professional doctoral degrees in the health related sciences during the period 1984-1993. Scientists working in eligible minority and women's educational institutions are encouraged to participate in this program. Since a primary purpose of the AREA program is to furnish support to those undergraduate institutions that provide student training in the sciences, principal investigators are encouraged to include the participation of students in the proposed Research Plan to the extent practicable.

INQUIRIES

Supplemental instructions/application forms

Those individuals and institutions meeting the eligibility requirements may contact the office named below to receive the AREA Program Guidelines and/or form PHS 398 application kit.

Academic Research Enhancement Award
Office of Grants Information
Division of Research Grants
Westwood Building, Room 449
Bethesda, MD 20892
Telephone: (301) 594-7248
FAX: (301) 594-7045

Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA program should be referred first to the Office of Sponsored Programs at the institution. Issues that remain AFTER consultation with the institutional Office of Sponsored Programs and that are NOT ADDRESSED in the AREA Program Guidelines may be addressed to:

Research Training and Special Programs Office
Office of Extramural Research
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-1968
FAX: (301) 496-0166

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.390. Grants will be awarded under authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Parts 52 and 74.

HIV-RELATED THERAPEUTICS IN DRUG USERS

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PA-94-023

P.T. 34; K.W. 0715008, 0404009, 0404000, 0785035, 0745070

National Institute on Drug Abuse
National Institute of Allergy and Infectious Diseases

PURPOSE

The purpose of this announcement is to stimulate research on HIV/AIDS-related therapeutics among infected drug users. There is a critical need to conduct studies which address HIV-related treatment issues among representative samples of drug users, in order to achieve improved clinical management of infected drug users. Research is needed on behavioral, clinical, and pharmacological aspects of treatment medications specific to drug users, including drug interactions, therapeutic efficacy and effectiveness, and psychosocial and behavioral parameters associated with success or failure of a therapeutic protocol.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This program announcement, HIV-Related Therapeutics in Drug Users, is primarily related to the priority area of National Health Promotion and Disease Prevention Objectives (HIV Infection, Immunization and Infectious Diseases). Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: (202) 783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and nonprofit public and private organizations, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from women and minority investigators are encouraged.

Foreign institutions are not eligible for FIRST awards (R29).

MECHANISMS OF SUPPORT

Support mechanisms for this announcement are the Individual Research Grants (R01), Small Grants (R03), First Independent Research and Transition (FIRST) Awards (R29), and competitive supplements (S01) to existing grants. Support for the small grant (R03) mechanism is available from the National Institute on Drug Abuse. For this program announcement, the National Institute of Allergy and Infectious Diseases will not utilize the small grant (R03) funding mechanism. Research grants are awarded to institutions on behalf of Principal Investigators. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Support for R01 awards for periods of up to five (5) years available and may be renewed at intervals or supplemented through the formal submission and review process. Continued support is subject to availability of funds and progress achieved. For information on the special requirements of the FIRST, Small Grant, and supplement Awards, contact program staff listed at the end of this announcement. Because the nature and scope of the research proposed in response to this Program Announcement may vary, it is anticipated that the size of an award will also vary.

RESEARCH OBJECTIVES

Background

Historically, drug users have been underrepresented in clinical trials, including established clinical trial protocols for HIV-related therapeutics. Underrepresentation has resulted in a lack of available research data specific to the unique issues of treating drug users with HIV-related therapeutics, including data on drug interactions, therapeutic efficacy and effectiveness, the impact of background health status and polydrug use, the psychosocial and behavioral parameters associated with success or failure of a therapeutic protocol, and access barriers to HIV-related medical therapies. Non-inclusion in HIV-related clinical trials has meant restricted access to FDA-approved therapies and has

limited available treatment options for drug users.

A 3-year collaboration (1990-1992) was undertaken by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute on Drug Abuse (NIDA) to enroll drug users in the established NIAID-sponsored AIDS Clinical Trials Group (ACTG) program. A focused effort at recruitment from established NIDA-sponsored drug treatment programs was made by selected ACTG sites. Although this initial effort was important in demonstrating the feasibility of enrolling drug users in formal efficacy trials, it was not intended to address the many issues specific to implementation of HIV-related therapeutic protocols among drug users. The current joint Program Announcement is an expansion of the NIAID/NIDA collaborative effort. Its purpose is to stimulate research on HIV-related therapeutics among a larger and more representative sample of drug users in a variety of settings. Under this announcement, research on HIV-related therapeutics includes both new and established antiretrovirals and immunotherapeutics, prophylaxis and therapy for HIV-related opportunistic infections, and treatments for other infectious diseases prevalent among drug users.

Areas of Research Interest

Areas of research that would be responsive to this announcement include, but are not limited to, the following:

1. Research on strategies to enhance recruitment and retention of in- and out-of-treatment drug users in protocols for HIV-related therapeutics (e.g., passive or active referral, voucher programs, referral through drug treatment settings and emergency rooms, outreach efforts and community diffusion programs, and comprehensive health programs).
2. Research on the interactions of HIV-related therapeutics with licit and illicit drugs (e.g., cocaine, alcohol, and heroin), and with methadone and other drug abuse treatment medications, including medications for dual diagnosis patients (e.g., studies of drug metabolism, toxicity, efficacy, and clinical side effects).
3. Studies of the efficacy of HIV-related therapeutics among both in- and out-of-treatment drug users in formal clinical trials protocols; studies of the long-term effectiveness of HIV-related therapeutics on clinical outcomes, HIV disease progression, and development of drug resistance, in the context of episodic or erratic patterns of adherence to treatment protocols and reversion to illicit drug use.
4. Evaluation of new or innovative strategies in drug-using populations, such as depot medications, to enhance adherence with HIV-related therapeutic protocols.
5. Evaluation of the effectiveness of linking trials of HIV-related therapeutics with drug abuse treatment and/or HIV-related research programs in a single setting; evaluation of the impact of such trials on enrollment and retention in drug abuse treatment.
6. Studies of behavioral issues that influence protocol recruitment, retention, and adherence in efficacy trials of HIV therapeutics, such as research on development and testing of predictor instruments to identify patient factors associated with good and poor adherence; studies of the determinants of adherence with HIV treatment regimens, including client decision-making processes and factors in patient adherence to clinical followup, taking of medications, adherence to protocols and related medical recommendations; studies of behavioral factors related to long-term adherence to HIV-related medical treatments among both in- and out-of-treatment drug users.
7. Studies of characteristics of the health care environment that promote utilization of available HIV-related therapeutics and long-term treatment participation, and the development of strategies to enhance access to and utilization of HIV-related medical therapies.
8. Research on cultural characteristics and gender differences in drug-using populations that influence acceptance of available HIV therapeutics and protocol recruitment, retention, and adherence; studies of special drug-using subgroups (e.g., women, adolescents, members of minority groups) that examine access barriers to delivery of HIV-related therapeutics.
9. Research to enhance the effectiveness of services to improve linkage between drug abuse treatment and HIV-related therapeutics, including the level of involvement of service providers, provision and coordination of services, and effective patient utilization of the case management system.
10. Research on development of effective information delivery strategies for in- and out-of-treatment drug users regarding new and established HIV-related treatments and protocols, in HIV testing and counseling programs, drug treatment centers, outreach programs, emergency rooms or other settings where drug users seek care; the impact of education regarding side effects, toxicities and the effectiveness of therapeutics on protocol recruitment, retention, and adherence.

STUDY POPULATIONS

NATIONAL INSTITUTES OF HEALTH (NIH) POLICY CONCERNING INCLUSION OF MINORITIES AND WOMEN AS SUBJECTS IN RESEARCH

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objective of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan and summarized in Section 5, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority

groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of the United States racial/ethnic minority populations (i.e., American Indian or Alaskan Natives, Asians or Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications must be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the receipt dates for applications for AIDS-related research found in the PHS form 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892 (Telephone: 301-594-7248). The number and title of the announcement must be typed in Item 2a of the face page of the application.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892*

*If an overnight courier is used, then the zip code is 20816.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator should be included with the application.

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as the central point for receipt of applications for most discretionary DHHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) on the basis of established Public Health Service referral guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit in accordance with the standard NIH peer review procedures. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the appropriate National Advisory Council, whose review will be based on policy considerations as well as scientific merit. Only applications recommended for further consideration by the Council may be considered for funding. Small grant (R03) and supplement applications receive a second level review by NIH staff.

AWARD CRITERIA

Applications recommended for further consideration by an appropriate Advisory Council will be considered for funding on the basis of overall scientific, clinical, and technical merit of the application determined by peer review, appropriateness of budget estimates, program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcomed. Direct inquiries regarding programmatic issues to:

Katherine Davenney, M.P.H.
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 11A-33
Rockville, MD 20857
Telephone: (301) 443-1801

George W. Counts, M.D.
Clinical Research Management Branch/TROP
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2A-04
Rockville, MD 20857
Telephone: (301) 496-8214

Direct inquiries regarding fiscal matters to:

Gary Fleming, J.D., M.A.
Grants Management Branch, OPRM
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

Mary C. Kirker
Grants Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B-22
Rockville, MD 20857
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of the Public Health Service Act, Section 301, and administered under PHS policies and Federal Regulations at Title 42 CFR 52 "Grants for Research Projects," Title 45 CFR Part 74 & 92, "Administration of Grants", and 45 CFR Part 46, "Protection of Human Subjects". Title 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. Title 42 Part 241(d), "Certificates of Confidentiality and Communicable Disease Reporting", may also be applicable to these awards. Applications submitted in response to this announcement are not subject to the intergovernmental review requirements of Executive Order 12372 of Health Systems Agency Review.

NIH LOAN REPAYMENT PROGRAM FOR AIDS RESEARCH

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PA-94-024

P.T. 34; K.W. 0715008, 1014006

National Institutes of Health

Application Receipt Dates: January 18 and June 20, 1994

PURPOSE

This notice is a republication, with significant modifications, of a February 26, 1993 (Vol. 22, No. 8) issuance on this subject. It is being reissued to emphasize its availability and to provide updated information regarding expanded eligibility criteria.

The Health Omnibus Programs Extension Act of 1993 (Public Law 100-607), which was enacted on November 4, 1988, directed the National Institutes of Health (NIH) to establish a program of educational loan repayment to attract additional investigators into Acquired Immunodeficiency Syndrome (AIDS) research. The NIH Revitalization Act of 1993 (Public Law 103-43), enacted June 10, 1993, modifies and expands this established program. The NIH Loan Repayment Program for AIDS Research (LRP), in order to increase the number of investigators conducting AIDS research at the NIH, invites interested health professionals to seek NIH employment in AIDS research positions and apply for LRP participation.

Since LRP participation is limited to NIH employees, interested individuals should be actively seeking NIH employment opportunities that conform to the eligibility criteria stated in this program announcement. Applicants must receive a written employment commitment and endorsement of the employing Institute, Center, or Division (ICD) of the NIH in order to be considered for the LRP.

As of June 10, 1993, individuals employed by the NIH during the period November 4, 1987 through November 3, 1988, are ELIGIBLE to apply and participate in the LRP subject to the other criteria and procedures described herein.

The LRP may pay a maximum of \$20,000 a year directly to a participant's lenders for qualifying educational debt during an initial, minimum two-year service period. The actual loan repayment is based, in part, on the availability of funding

as well as the proportion of the participant's qualifying educational debt relative to their NIH basic pay or stipend. Qualifying educational debt amounts in excess of 50 percent of the debt threshold (see ELIGIBILITY REQUIREMENTS below) will be considered for repayment.

Since such repayments to lenders are considered income for the participant and increases his/her Federal tax liability, the LRP also makes payments, equal to 39 percent of the total loan repayments, directly towards the participant's Internal Revenue Service (IRS) account. The LRP may make additional tax reimbursements to those participants who show an increase in State and/or local tax liability. Benefits are paid in addition to a participant's annual NIH basic pay or stipend.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement describes the NIH Loan Repayment Program for AIDS Research, a program which is related to the priority area of HIV infection. Those interested may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

An applicant to the LRP is accepted for LRP participation when his/her qualified AIDS research assignment is approved by the AIDS Research Loan Repayment Committee (LRC) and his/her contract is executed. Specific LRP applicant and participant eligibility criteria include the following:

1. Applicants must be citizens or permanent residents of the United States;
2. Applicants must have a Ph.D., M.D., D.O., D.D.S., D.M.D., D.V.M., or equivalent degree;
3. Applicants must have qualified educational debt in excess of 20 percent of their annual NIH basic pay or stipend on the date of program eligibility (DEBT THRESHOLD), resulting from governmental or commercial loans obtained to support their undergraduate and/or graduate education;
4. Individuals with existing service obligations to Federal, State, or other entities will NOT be considered for the LRP unless deferrals are granted for the length of their LRP service obligation;
5. Applicants must be appointed under a temporary or permanent employment mechanism which allows their employment with the NIH to last a minimum of two years;
6. Individuals who are not NIH employees, such as Visiting Fellows, Intramural Research Training Award (IRTA) recipients, National Research Service Award (NRSA) recipients, Guest Researchers or Special Volunteers, NIH National Research Council (NRC) Biotechnology Research Associates Program participants, and Intergovernmental Personnel Act (IPA) participants, may NOT participate in the LRP; and
7. Applicants will NOT be excluded from consideration under the LRP on the basis of race, color, creed, religion, sex, handicap, age, national origin, or political affiliation.

In addition, in order to qualify for repayment, LRP applicants' debts are subject to the following limitations and restrictions:

The LRP will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, and local) and commercial educational loans obtained by participants for the following: (1) undergraduate, graduate, and health professional school tuition expenses; (2) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses as determined by the LRP.

The following loans are NOT repayable under the LRP:

1. loans not obtained from a Government entity or commercial lending institution, such as loans from friends, relatives, or other private individuals;
2. loans for which contemporaneous documentation is not available;
3. loans or portions of loans obtained for educational or living expenses that exceed the "reasonable" level as determined by the standard school budget for the year in which the loan was made, and are not determined by the LRP to be reasonable based on additional documentation provided by the applicant;
4. loans, financial debts, or service obligations incurred under the following programs: Physicians Shortage Area Scholarship Program, National Research Service Award Program, Public Health and National Health Service Corps Scholarship Training Program, National Health Service Corps Scholarship Program, Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Program, Indian Health Service Scholarship Program, and similar programs which provide loans, scholarships, loan repayments, and other awards in exchange for a future service obligation;
5. loans in default or not in a current payment status; and
6. loan amounts that participants have paid or were due to have paid prior to the program eligibility date.

Repayments will only be made for loans in a current payment status. During lapses in loan repayments, due either to program administrative complications or a break in service, participants are wholly responsible for making payments or any other arrangements that maintain loans in a current payment status. Penalties assessed to participants as a result

of LRP administrative failures to maintain current payment status may be considered for reimbursement.

RESEARCH OBJECTIVES

The LRP is designed to attract additional investigators into AIDS research. The LRP intends to fund individuals conducting AIDS research as described in the following paragraphs, which contain the "Activities Constituting AIDS Research" criteria as adopted by the LRC, October 13, 1992:

"The following parameters define whether a proposed research assignment meets the criteria for coverage under the NIH Loan Repayment Program for AIDS Research - that is, whether the incumbent will be "primarily" engaged in AIDS research. "Primarily" engaged in AIDS research is defined as AIDS research activities that constitute at least 80 percent of a researcher's time. Clinical Associates, whose intent is to primarily engage in AIDS research, must engage in qualified AIDS research for at least three months in the first year of their program, with a total of fifteen months of qualified AIDS research during their two-year contract.

"AIDS research includes studies of the human immunodeficiency virus (HIV), the pathophysiology of HIV infection, the development of models of HIV infection and its sequelae, cofactors predisposing to HIV infection and AIDS, or its sequelae, and the development of vaccines and therapeutics. More specifically, the following research activities are included: (1) studies of HIV and related retroviruses; (2) studies of the mechanism(s) by which HIV and related retroviruses establish infection and infect host cells; (3) studies of the mechanism(s) by which HIV and related retroviruses cause disease, including studies of the immune deficiency induced by HIV and related retroviruses; (4) studies of the pathophysiology of host response to HIV infection; (5) studies of in vivo or in vitro models of human HIV infection and its sequelae; (6) epidemiologic studies of HIV and related retrovirus infection; (7) clinical trials involving prophylaxis or therapy for HIV infection or its sequelae; (8) preclinical studies aimed at the development of therapy for or prevention of HIV infection and the immunodeficiency caused by HIV infection and its sequelae; (9) cofactors predisposing to acquiring HIV infection and/or the progression of HIV-related disease; (10) basic studies and clinical trials involving vaccines, or other immunological or chemotherapeutic interventions for the prevention of HIV infection and its sequelae; (11) studies into the transmission of HIV involving high risk behaviors and research concerning the interruption of transmission by behavioral change and pharmacologic intervention; and (12) basic studies of the societal impact of and response to the HIV/AIDS epidemic, including subgroups within the population.

"AIDS researchers include scientists who are intellectually engaged in the process of providing scientific direction and guidance in programs of original AIDS research, specifically epidemiologists, statisticians, and others who are involved in the design and conduct of research studies. The duties of such scientists may include the generation and design of studies and the collation and analysis of data; and/or the preparation and publication, as author or co-author, of studies in peer-reviewed journals.

"AIDS researchers also include physicians who are providing care for HIV-infected individuals who are subjects of HIV-related research."

APPLICATION PROCEDURES

An initiating official, who may be a laboratory or branch chief, must recommend an individual for application to the LRP, and the Institute, Center, or Division (ICD) Scientific Program Director and ICD Director must concur. Since LRP participation is contingent, in part, upon employment with the NIH, candidates may not be recommended for loan repayment by an ICD until a firm employment commitment has been made by the recommending ICD's Personnel Department.

ICD Loan Repayment Program Coordinators forward recommended applications to the Director, LRP, who submits eligible applications for consideration and approval/disapproval by the LRC. Recommended candidates may forward financial information directly to the Director, LRP.

At the conclusion of the initial contract, participants may reapply and be considered for subsequent, one-year continuation contracts. Continuation contracts are based upon the same review criteria as the initial contract, in addition to a description of AIDS research accomplishments made during the initial contract. These continuation contracts are approved on a year-to-year basis and contingent upon the appropriation and availability of funds.

REVIEW CONSIDERATIONS

The LRC reviews the scientific research portions of eligible LRP applications. The LRC, which is composed of intramural and extramural scientific staff, reviews, ranks, and approves or disapproves applications. LRC approval, in part, is based on the appropriateness of the research assignment to the LRP's AIDS research criteria (see above) and the scientific merit of the research. In addition, the credentials provided in the application are reviewed and ranked to assess the applicant's potential to conduct qualified AIDS research.

LRP program staff review and verify the financial portions of eligible applications and determine projected funding levels. Actual funding is dependent upon LRC approval and the terms of the LRP service contract.

AWARD CRITERIA

The award of funds for approved applications is contingent, in part, upon the availability of appropriated or allocated funds. Funds will not be awarded to disapproved applications. In return for the repayment of their educational loans, participants must agree (1) to be "primarily" engaged in qualified AIDS research, which is described above in the "Activities Constituting AIDS Research" criteria, as NIH employees for a minimum period of two years; (2) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); (3) pay monetary damages as required in cases where the initial contract is breached; and (4) all other provisions agreed upon in their contracts. Substantial monetary penalties will be imposed for breach of contract.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Information regarding the LRP may be obtained by calling or writing the following:

Mr. Marc S. Horowitz, J.D.
Office of AIDS Research
National Institutes of Health
7550 Wisconsin Avenue, Suite 102
Bethesda, MD 20892-9905
Telephone: (800) 528-7689

AUTHORITY AND REGULATIONS

The LRP is described in the Catalog of Federal Domestic Assistance under number 93.936. Awards are made under authorization of section 487A of the PHS Act (42 U.S.C. 288-1), as amended by section 634 of the Health Omnibus Programs Extension of 1988 (P. L. 100-607) and section 1611 of the NIH Revitalization Act of 1993 (P.L. 103-43). This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs, and was granted clearance from the Office of Management and Budget (OMB) (0925-0361), under the requirements of the Paperwork Reduction Act of 1980, on June 15, 1990.

POSTDOCTORAL TRAINING IN ALTERNATIVE MEDICINE

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PA-94-025

P.T. 44; K.W. 0720005, 0710030

Office of Alternative Medicine
National Institutes of Health

Application Receipt Dates: April 5, August 5, and December 5

PURPOSE

The Office of Alternative Medicine (OAM) is planning to fund, through the various Institutes at the National Institutes of Health (NIH), individual postdoctoral training awards for FY 94 using the National Research Service Award (NRSA) mechanism. The purpose is to provide a cadre of investigators capable of conducting systematic studies on safety, efficacy, cost-effectiveness, or mechanisms of action of unconventional methods for treating major diseases and promoting well-being. This training is expected to attract postdoctoral candidates who are in the early stages of their careers. They will have obtained expertise in conventional research methodology and some familiarity with/or interest in alternative medical procedures. Prospective trainees will be expected to form an alliance with established researchers to provide a mutual learning experience.

This program announcement (PA) on Alternative Medicine is an abbreviation of a larger, NIH-wide PA on NRSA Individual Postdoctoral Fellows, which should be requested from the contact person listed below.

ELIGIBILITY REQUIREMENTS

Individuals must be citizens or noncitizen nationals of the United States, or have been lawfully admitted to the U.S. for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card 1-551 or in possession of other legal verification of such status.) Prior to beginning the award the applicant must have received a Ph.D., M.D., D.O., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D, Dr. P.H., D.N.S., D.Pharm., D.S.W., or Psy. or equivalent doctoral degree from an accredited domestic or foreign institution.

Before submitting a fellowship application, the applicant must arrange for appointment to an appropriate, accredited university, hospital, or other institution with facilities including staff for postdoctoral training. This may include institutions that train in areas outside conventional medicine such as acupuncture or chiropractic. The candidate should be accepted by a sponsor who will actively supervise the training. The sponsor should have research experience in clinical medicine and/or basic pre-clinical research along with an involvement in the evaluation of alternative medicine. Thus, the sponsor should be qualified to supervise in the application of rigorous study design to the assessment of individual alternative therapies. Because of the novelty of some procedures, it is recognized that the sponsor may not have reached the level of "senior" investigator in a particular field of alternative medicine.

Applicants proposing training at their doctorate institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would increase their scientific background relating to Alternative Medicine.

MECHANISM OF SUPPORT

The mechanism of support is the Individual National Research Service Award. Individuals may request up to 3 years of aggregate NRSA support at the postdoctoral level. The stipend level for the first year of NRSA support is determined by the number of years of relevant postdoctoral experience at the time the award is issued. The range of support is from \$18,600 (less than 1 full year of experience) to \$32,300 (7 or more years of experience). Relevant experience includes research experience, teaching, internship, residency, and clinical duties.

Supplementation, when provided, must not require obligation from the fellow. Under no circumstances may PHS grant funds be used for supplementation. NIH will provide an institutional allowance of \$3,000 per 12-month period to non-Federal nonprofit sponsoring institutions to help defray such awardee expenses as tuition and fees, self-only health insurance,

research supplies, equipment, travel to scientific meetings, and related items. For individuals sponsored by Federal laboratories, or for-profit institutions, the NIH will provide up to \$2,000 for scientific meeting travel expenses, self-only health insurance, tuition fees, and books. Fellows in the first twelve months of postdoctoral NRSA support will incur a service obligation of one month for each month of support. Additional information is contained in the NIH Guide, Vol 22, July 30, 1993.

It is expected that four to six awards in Alternative Medicine will be made in FY 1994.

RESEARCH OBJECTIVES

The OAM was established in 1992 to evaluate and determine the efficacy of various unconventional, alternative or complementary medical practices. A recent survey demonstrated that as many as 34 percent of adults utilized at least one alternative, therapy for the treatment of a serious or bothersome medical condition during the previous year (Eisenberg, D. et al, New England J. Med. 328: 246-252, 1993). The cost for services provided by alternative practitioners is estimated to be more than \$13 billion a year. Many of these interventions have not, however, been subjected to scientific scrutiny using conventional research methods. Existing research in this area is limited by a paucity of well designed trials, and there are few research data bases which allow for systematic review or meta-analysis of treatment efficacy. OAM feels that it is important to better understand if any of these therapies benefit the patients that use them.

Unconventional practices include medical interventions that are not widely taught at medical schools or are not generally available at hospitals within the United States. For the most part, such treatments are not reimbursable by third party (insurance companies) payers. Examples of areas of interest include, but are not limited to: acupuncture; homeopathy; structural manipulation including chiropractic/massage; visual imagery, relaxation techniques, meditation, herbal therapies, or diet and life style. The Office is especially interested in alternative procedures in the treatment of life threatening diseases, e.g., women's breast cancer or AIDS-HIV and the subsequent impact on either/and: a) course of disease; b) wellness/quality of life/ prevention; c) statistical/population disease trends d) basic biological systems. However, any particular health problem such as arthritis, depression, drug or alcohol addiction, or heart disease is acceptable.

APPLICATION PROCEDURES

Applicants should submit a completed Application for Public Health Service Individual National Research Service Award (PHS 416-1 rev. 10/91), including with the application at least three letters of reference.

Application kits can be obtained from the following address:

Grants Information Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
Bethesda, MD 20892
Phone: (301) 594-7248

Applicants and sponsoring institutions must comply with policies and procedures governing the protection of human subjects, the humane care and use of live vertebrate animals, and the inclusion of women and minorities in study populations.

REVIEW CONSIDERATIONS

The review criteria will focus on the following main components: a) the applicant's academic preparation; b) the scientific merit of the proposed research including the clarification of treatment efficacy of a particular alternative medical procedure; c) training potential for the student; d) the training resources and environment, including the sponsor. Following the initial review, the grant application will be assigned to one of the institutes based on the major health problem to be evaluated; e.g., alternative procedures evaluating cancer would be assigned to the National Cancer Institute (NCI). A second level of review will be provided by a committee or staff from the relevant institute and the OAM.

AWARD CRITERIA

The following criteria will be used by the NIH in making awards: a) individual review group (IRG) recommendation of the overall merit of the application; b) relevance of the application to the research priorities of the Institute and the OAM along with program balance; c) availability of funds.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issue or question(s) from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Dr. John Spencer
Office of Alternative Medicine
National Institutes of Health
6120 Executive Blvd., Suite 450
Rockville, MD 20892-9904
Telephone: (301) 402-4333
FAX: (301) 402-4741

AUTHORITY AND REGULATIONS

NRSAs are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288) and Title 42 of the Code of Federal Regulations, Part 66.

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANT

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PAR-94-026

P.T. 34; K.W. 0735000, 1014006

National Center for Research Resources

Application Receipt Date: March 24, 1994

PURPOSE

The National Center for Research Resources (NCRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant (SIG) Program initiated in Fiscal Year 1982. The (1990) "National Report on Academic Research Equipment and Equipment Needs for Biological Sciences," cosponsored by the National Institutes of Health (NIH) and the National Science Foundation, identified research equipment of the type provided through this program as top-priority. The objective of the program is to make available to institutions with a high concentration of NIH-supported biomedical/behavioral investigators research instruments which can only be justified on a shared-use basis and for which meritorious research projects are described.

ELIGIBILITY REQUIREMENTS

Under the general research support authority of Section 301 (a)(3) of the Public Health Service Act, BRS Shared Instrumentation Grant awards are made to public and non-profit institutions only. For purposes of these guidelines, an "institution" is defined as the organizational component identified in item 14 on page 1 of the Form PHS 398 (rev. 9/91), for which descriptive information is provided on page 15 in the PHS 398 kit. These institutions include health professional schools, other academic institutions, hospitals, health departments, and research organizations. Federal institutions, foreign institutions, and for-profit institutions are not eligible. Awards are contingent on the availability of funds.

An eligible institution may submit more than one application for different instrumentation for the March 24, 1994, deadline. However, if several applications are submitted for similar instrumentation from one or more eligible institutions on the same campus of a university, documentation from a high administrative official must be provided, stating that the several applications are part of a campus-wide institutional plan, not an unintended duplication.

MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants (S10) provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least \$100,000 per instrument or system. The maximum direct cost award is \$400,000. Indirect costs will not be provided. Because the nature and scope of the instruments which may be requested will vary, it is anticipated that the size of an award will vary also.

RESEARCH OBJECTIVES

This program is designed to meet the special problems of acquisition and updating of expensive shared-use instruments which are not generally available through other NIH mechanisms, such as the regular research project, program project, and center grant programs, or the Biomedical Research Technology Grant Program. Proposals for the development of new instrumentation will not be considered.

Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment, personal computers, personal workstations, printers, and ethernet interfaces. Proposals for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of NIH-supported investigators.

Awards will be made for the direct costs of the acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel, and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$400,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, the application should describe the proposed source(s) of funding for the balance of the cost of the instrument. Documentation of the availability of the remainder of the funding, signed by an appropriate institutional official, must be presented to NCRR prior to the issuance of an award. Requests for a multiple instrument purchase totalling over \$400,000 must specify and justify which instrument(s) should be supported within the \$400,000 ceiling.

Applicants proposing the direct purchase of an instrument that the institution has secured or is planning to secure via a leasing agreement are strongly encouraged to consult with their institutional sponsored projects office regarding applicable NIH policy prior to executing the leasing agreement. If the leasing agreement was executed more than one year prior to submission of the SIG application, the applicant must provide strong justification for the requested Federal funds. Further, the instrument must be considered state-of-the-art at the time of submission of the SIG application.

A major user group of three or more investigators should be identified. A minimum of three major users must be Principal Investigators on NIH peer reviewed "regular research grants" at the time of the application and award. For purposes of this program "regular research grants" are defined as those grants awarded with the following activity codes: P01, R01, R29, R35, R37, and S06. Cooperative agreements, with activity code U01, are also included in this definition. The application must show a clear need for the instrumentation by projects supported by multiple NIH research awards

and demonstrate that these projects will require at least 75 percent of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. NIH extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument should be made available to other users upon the advice of the internal advisory committee. These users need not be NIH awardees, but priority should be given to NIH-supported scientists engaged in biomedical/behavioral research.

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered, and for continued support for the maximum utilization and maintenance of the instrument in the post-award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

If a grant award is made, a final progress report will be required that describes the use of the instrument, listing all users and indicating the value of the instrumentation to the research of the major users and to the institution as a whole. This report is due within 90 days following the end of the project period.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

1. Form page 1 (Face page of the application) -

Item 1. Name the type of instrument requested. (Note at the bottom of the face page if a duplicate application has been sent to another agency.)

Item 2. Check the box marked, "yes," and write in the number of this announcement and "NCRR-BRS SHARED INSTRUMENTATION GRANT."

Item 4. If human subjects are involved in the research, follow the instructions for completing Item 4 on the Face Page of Form PHS 398, certifying that an Institutional Review Board (IRB) approved by PHS has reviewed and approved the protocols involving human subjects. If the protocols are ongoing and have already received prior IRB review and approval within one year of the submission date of this application, then additional IRB review is not necessary. However, this fact must be noted in Item 4 on the Face Page, and, if space is insufficient, the date(s) of prior IRB review and approval of each protocol involving human subjects should be listed in the "Research Plans."

Item 5. If live vertebrate animals are involved in the research, follow the instructions for completing Item 5 on the Face Page of Form PHS 398, verifying that an Institutional Animal Care and Use Committee (IACUC) approved by PHS (OPRR) has reviewed and approved the protocols involving animals. If the protocols are ongoing and have already received prior IACUC review and approval within three years of the submission date of this application, then additional IACUC review is not necessary. However, this fact must be noted in Item 5 on the Face Page and, if space is insufficient, the date(s) of prior IACUC review and approval of each protocol involving animals should be listed in the "Research Plan."

Item 6. Write in April 1, 1995 - March 31, 1996.

Item 8A. Use this block to give the total amount requested from NCRR for this instrument or system.

Item 14. Insert the appropriate code identification.

2. Form page 2. Complete the abstract as directed. Under "Personnel engaged on project", give data on the Principal Investigator and the major user group as required.

3. Form page 4. Describe the instrument requested including manufacturer and model number. The model chosen should be justified by comparing its performance with other available instruments. Provide a detailed budget breakdown of the main equipment and accessories requested including tax and import duties, if applicable. An itemized quote from a vendor should be included. If a project involves a potential biohazard, funds for accessory containment equipment for the instrument or instrument system may be included in the requested budget.

4. Form page 5. Budget Estimates for All Years. Not applicable; do not complete.

5. Form page 6. Biographical Sketch. In addition to the personnel listed on page 2, include a biographical sketch of the person(s) who will be in charge of maintenance and operation of the instrument and a brief statement of the qualifications of the individual(s). Biographical sketches should not exceed 2 pages for each individual.

6. Form page 7. Other Support. Provide the requested information for each major user.

7. Section 2 of the application. (If this is a revised application, note the special instructions in the PHS 398 kit regarding completion of Section 2 of the application.)

Provide information relative to the points identified under criteria for review including:

a. Inventory similar instruments existing at the institution or otherwise accessible; describe (with supporting documentation) why they are unavailable or inappropriate for the proposed research and provide a clear justification

why new or updated equipment is needed, including accessories.

b. The major users should describe their research projects and indicate how the requested instrumentation and/or accessories would enhance the progress of their research projects. While most projects are included in currently funded applications, some represent new directions. In the case of funded projects, the description should not exceed four pages per user but should point out the benefit of the proposed instrument to the research objectives of each major user. New directions and their requirements for the proposed instrumentation should be described in sufficient detail to allow adequate review (including preliminary data or supplemental materials). Use a table to list the names of the users, brief titles of the projects, the NIH grant numbers and the estimated percentage of use. List the page number of this table under "Table of Contents" (Form page 3) after "Resources and Environment." Make a separate table to indicate the major users' needs for requested accessories. If possible, each user should highlight those publications that demonstrate the user's expertise in using the requested instrumentation.

c. Describe the organizational plan including the internal advisory committee for administration of the grant.

d. Submit a specific plan for long-term operation and maintenance of the instrument. Provide documentation (e.g., separate letters signed by appropriate institutional officials) describing the required institutional commitment in support of the proposed plan.

Applications must be received by March 24, 1994. Applications received after this date will not be accepted for review in this competition. The original and three copies of the application, together with four copies of any appendix material, should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

Two copies of the application and one copy of any appendix material should be addressed to:

Biomedical Research Support Program
National Center for Research Resources
National Institutes of Health
Westwood Building, Room 848
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and for program considerations by the National Advisory Research Resources Council (NARRC) of the NCRR. Approximately half of the applications will be reviewed at the September 1994, NARRC meeting and the remainder at the NARRC meeting in February 1995. The Council date will not affect funding decisions.

Criteria for review of applications include the following:

- o The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
- o The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
- o The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.
- o The institution's commitment for continued support of the utilization and maintenance of the instrument.
- o The benefit of the proposed instrument to the overall research community it will serve.

AWARD CRITERIA

In making funding decisions, the NCRR will give consideration to ensure program balance among various types of instruments supported and/or geographic distribution of awards.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic or scientific issues to:

Abraham Levy, Ph.D.
Biomedical Research Support Program
National Center for Research Resources
Westwood Building, Room 848
Bethesda, MD 20892
Telephone: (301) 594-7947

Direct inquiries regarding fiscal matters to:

Ms. Mary V. Niemiec
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 594-7955

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance number 93.337, Biomedical Research Support. Awards will be made under authorization of the Public Health Service Act, Titles III and IV (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 287) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUM

MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

NIH GUIDE, Volume 23, Number 1, January 7, 1994

PA NUMBER: PAR-94-017

P.T. 34, FF; K.W. 0710030, 0715035

National Cancer Institute

The National Cancer Institute (NCI) would like to correct the above-titled Program Announcement, PAR-94-017, published in the NIH Guide, Vol. 22, No. 44, December 10, 1993, as follows.

The third paragraph under "ELIGIBILITY REQUIREMENTS" is modified as follows:

Applicants may not accept other PHS research grant support or its equivalent when applying for a Minority School Faculty Development Award. However, applicants may apply for and accept other research grant support subsequent to being awarded the Minority School Faculty Development Award.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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Building 31, Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 2
January 14, 1994

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

IMMUNOLOGICAL BLOOD SAMPLE PREPARATION AND ASSAYS

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFP AVAILABLE: NCI-CB-46207-82

P.T. 34; K.W. 0715035, 0740075, 0755010

National Cancer Institute

The National Cancer Institute (NCI) is soliciting proposals from offerors with the capability to provide immunological testing support services in the cancer vaccine field. Testing will be of patient and/or non-human primate blood. The assays required will include: isolation and freezing of peripheral blood mononuclear cells, lymphoproliferation assays, cytokine assays, T cell phenotyping, cytotoxic T cell assays, and assays for antigen, antibody, and antigen-antibody complexes. This is a new requirement. Some limited testing has been provided through the use of purchase orders.

The first recombinant anti-cancer vaccine developed by the NCI has already begun Phase 1 clinical trials. There are other recombinant anti-cancer vaccines that will also be tested in non-human primates and in clinical trials. Common to all these trials and preclinical testing is the fact that active specific immunotherapy approaches are based on the potentiation of the cellular and/or the humoral immune response by active immunization, the induction of cellular and/or humoral responses, and the subsequent role of the antitumor activity. This information is critical to evaluation of the vaccines. This necessitates a comprehensive and uniform evaluation of the immunological responses, since many of these studies will be carried out at different institutions and companies.

The Government will supply patient and/or non-human primate blood to the contractor for analysis. These samples will be identified by code to ensure patient confidentiality and blinded analysis. Blood analyses are separated into the following tests: (1) isolation and freezing of peripheral blood mononuclear cells; (2) immunoresponse assays including: (2a) lymphoproliferation assays, (2b) culture supernatant harvests, (2c) cytokine assays (IL-2, IL-6, IFN-gamma, TNF-alpha); (3) T cell phenotyping (CD3, CD4, CD8, CD4/C); (4) cytotoxic cell assays including: (4a) generation of EBV immortalized B cell lines, (4b) preparation of target cells, (4c) preparation of effector cells, (4d) cytotoxic assays; (5) serologic assays including: (5a) separation of serum from blood samples, (5b) anti-tumor associated antigen immunoglobulin response, (5c) serum tumor associated antigen levels, (5d) immune complex determination. The NCI project officer will order the assays to be performed on each individual [BLOOD] sample. The orders, therefore, may be only one assay of all of the above, per individual sample. It is anticipated that the proposed contract will be for a five-year period of performance.

INQUIRIES

Solicitation will be issued on or about January 12, 1994, and responses will be due 30 days thereafter. All responsible sources may submit a proposal that will be considered by the NCI. No collect calls will be accepted. Requests for this solicitation must be in writing and reference NCI-CB-46207-82. Requests are to be addressed and mailed or faxed to:

Michelle Scala
Research Contracts Branch, PSCS
National Cancer Institute
Executive Plaza South, Room 638
Bethesda, MD 20892
Telephone: (301) 402-4509
FAX: (301) 402-4513

PHASE I CLINICAL TRIALS OF ANTICANCER AGENTS

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFP AVAILABLE: NCI-CM-57208-74

P.T. 34; K.W. 0755015, 0740020, 0710100

National Cancer Institute

The Cancer Therapy Evaluation Program (CTEP) of the Division of Cancer Treatment (DCT), National Cancer Institute (NCI), is seeking organizations with the capabilities and facilities to provide Phase I clinical trials of investigational new agents. Specifically, the organizations will perform studies to: (a) define the acute toxicities of new anticancer agents in patients with advanced cancer; (b) re-define the acute toxicities and pharmacokinetics of existing anticancer agents administered in combination with colony stimulating factors and other toxicity ameliorating agents that may facilitate the exploration of more effective doses and schedules; (c) provide information on the pharmacologic characteristics of selected antitumor agents; (d) define treatment regimens for evaluation of antitumor activity in Phase II trials; (e) establish appropriate Phase II doses in special patient populations, such as those with impaired end-organ function or with heavy pretreatment, geriatric populations, and to explore pharmacokinetic and pharmacodynamic differences based on gender, race, or ethnic group; (f) obtain preliminary information on pharmacokinetic/pharmacodynamic correlations that can then be extended in Phase II trials; and (g) incorporate ancillary basic laboratory studies, when possible and appropriate, to enhance our understanding of the biochemical and/or biological mechanisms of drug actions. The Contractor will accrue at least 50 contract credits per year to at least three active Phase I trials per year for five years. Pharmacokinetics and/or correlative laboratory studies will be a standard feature of these studies. All patients for these studies must be treated at the offeror's own institution. Offerors who submit proposals must demonstrate the accrual of at least 50 evaluable adult cancer patients to IRB approved Phase I cancer treatment protocol studies conducted at the offeror's institution during calendar year 1993.

The proposed acquisition is a recompetition of six existing contracts currently held by the following: N01-CM-07301, University of Chicago; N01-CM-07302, Johns Hopkins University; N01-CM-07303, University of Maryland; N01-CM-07304, Mayo Foundation; N01-CM-07305, University of Texas Health Science Center, N01-CM-07306, University of Wisconsin. It is anticipated that six awards will be made and that the resulting contracts will be awarded on an incrementally funded basis for a period of 66 months.

INQUIRIES

RFP NO. NCI-CM-57208-74 will be issued on or about January 13, 1994 and proposals will be due approximately March 29, 1994. All responsible sources may submit a proposal that will be considered by the NCI. No collect calls will be accepted. Requests for this solicitation must be in writing and reference RFP No. NCI-CM-57208-74. Requests are to be addressed and mailed or faxed to:

Odessa S. Henderson
Research Contracts Branch, TCS
National Cancer Institute
Executive Plaza South, Room 603
Bethesda, MD 20892
Telephone: (301) 496-8620

MINORITY DISSERTATION RESEARCH GRANTS IN AGING

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFA AVAILABLE: AG-94-004

P.T. 34, FF; K.W. 0710010, 0710030

National Institute on Aging

Application Receipt Date: March 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Small grants to support doctoral dissertation research will be available for minority doctoral candidates. Grant support is designed to aid completion of dissertation research of minority investigators and to encourage individuals from a variety of academic disciplines and programs to study problems in aging and issues related to aging.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas, several of which are related to aging. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

The applicant investigator applying for a dissertation research grant must be a member of an ethnic or racial minority group that is underrepresented in biomedical research, enrolled in an accredited doctoral degree program in the biomedical, social, or behavioral sciences and must have approval of the dissertation topic by a named dissertation committee or other formal group for that purpose. The student must also be conducting or intending to conduct dissertation research on aging or problems related to aging. Research topics would fit within one or more of the program areas described in the RFA. The applicant institution must be domestic and will administer the grant on behalf of the proposed investigator. The applicant investigator for dissertation research grant support must be a citizen of the United States or hold a permanent resident visa.

MECHANISM OF SUPPORT

The mechanism of support is the NIH small grant (R03). Dissertation research grants will be administered in accordance with the U.S. Code Annotated, Title 42, Part B, Section 284. Awards will depend on the availability of funds. Applicant investigators should request support for the amount of time necessary to complete the dissertation. However, a dissertation research grant usually is awarded for a period of 12 months or less but may be awarded for up to 24 months. The total direct costs of the entire project may not exceed \$25,000. An application that exceeds this amount will be returned. Allowable costs include the investigator's salary (not to exceed \$10,000); direct research project expenses such as travel, data processing, supplies, and dissertation costs. No tuition or permanent equipment is allowed.

FUNDS AVAILABLE

The NIA anticipates funding approximately 20 grants with a total program cost of up to \$600,000.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The RFA and special guidelines for dissertation grant applications must be requested from the program staff listed under INQUIRIES. The application is to be submitted on form PHS 398 (rev. 9/91) available from the university office of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The special instructions described here and in the application kit must be followed. Applications will be assigned to the NIA for review and possible funding.

Applications must be received by March 18, 1994. The original application including a detailed narrative project description (not to exceed 10 pages) and letters and three copies must be sent directly to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

An additional two copies must be sent to:

Chief, Scientific Review Office
National Institute on Aging
Gateway Building, Suite 2C212
Bethesda, MD 20892
ATTN: Minority Dissertation

A letter from the faculty committee or university official directly responsible for supervising the development and progress of the dissertation research must be submitted with the application. Details of the letter are given in the RFA.

REVIEW CONSIDERATIONS

Dissertation research grants are competitive. Review will be conducted by a special committee convened by the NIA. Review results and funding decisions will be announced within six months after the submission date.

AWARD CRITERIA

The anticipated date of award is September, 1994. Final funding decisions are based on the recommendations of the reviewers, the relevance of the project to NIA priorities, and the availability of funds.

INQUIRIES

Interested applicants may request the RFA, additional guidelines for preparing the application, and discuss the suitability of the mechanism by letter or by telephone with the person named below. The applicant subsequently will be referred to the relevant NIA program director to discuss the suitability of the research topic.

Mr. Charles A. Blackwood
Office of Extramural Affairs
National Institute on Aging
Gateway Building, Suite 2C218
Bethesda, MD 20892
Telephone: (301) 496-9322

Direct inquiries relating to fiscal matters to:

Mr. Joseph Ellis
Grants Management Officer
National Institute on Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.366. Awards are made under authorization of the Public Health Service Act Title IV, Part A (Public Law 79-410, as amended by Public Law 99-158, 42 DSC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to NIA research grant programs.

CENTERS ON THE DEMOGRAPHY OF AGING

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFA AVAILABLE: AG-94-005

P.T. 04; K.W. 0710010, 0413001, 0408006

National Institute on Aging

Letter of Intent Receipt Date: February 1, 1994
Application Receipt Date: March 31, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA): IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Aging (NIA) invites applications for Exploratory Center Grants in the area of the demography of aging. The Demography and Population Epidemiology Cluster within the Behavioral and Social Research Program supports research and training in the dynamics of population aging using a variety of demographic and economic approaches. Congress has urged the further development of research on the demographic aspects of population aging. These center grants will support the infrastructure necessary for research, new program development in selected areas, the development of innovative networks of researchers, and enhanced sharing of specialized databases including rapid application of research results from these databases.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Centers on the Demography of Aging, is related to several priority areas including chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applications from minority individuals and women are encouraged.

A P20 core grant assumes substantial pre-existing research activity on population aging at the institution. A minimum of one peer-reviewed and externally funded currently active research project directly within the area of demography or economics of health and aging is required. Sub-projects on P01 grants may be counted as individual projects.

MECHANISM OF SUPPORT

The support mechanism for this program is the Exploratory Center Grant (P20).

FUNDS AVAILABLE

The NIA expects to make between four and eight awards in response to this RFA and anticipates that an estimated \$1,500,000 in total costs per year for five years will be committed. Although this program is provided for in the financial plans of the NIA, awards are contingent on the availability of funds. Direct costs of the awards are expected to vary between \$75,000 and \$250,000. No request may exceed \$350,000 total costs in the first year, with a four percent per annum inflation increase allowable in subsequent years. However, in addition to the \$350,000 limit, up to \$25,000 in direct costs (plus any indirect costs) may be separately requested for the functions of a coordinating center.

RESEARCH OBJECTIVES

Each proposed Center should focus on one or more scientific themes or areas directly relevant to population aging. Important initiatives and priorities within population aging include:

- o forecasting life and active life expectancies, health, medical services and long term care usage, especially for the very old;
- o medical demography of chronic diseases including the dementias and the integration of medical demography with epidemiology, population genetics, early life determinants of health in old age, nutrition, and health services research;
- o the cost and impact of aging-related illnesses and disabilities (especially in the last years of life), and cost-benefit analyses in terms of added health expectancy;
- o demographic or economic evaluations of the impact of DHHS or other public policies (such as changes in retirement-benefit eligibility ages, or the proposed health care reform) on the health and well being of the older population, including the development of relevant macro- and microsimulation models;
- o demographic analyses of the aging of disadvantaged components of the population, including the Black and Hispanic populations;
- o the macro and micro dynamics of inter-generational exchanges associated with population aging;
- o demographic and survey methods for studying elderly populations;
- o the determinants and consequences of retirement; comparative research on retirement and income support policies in other countries; the dynamic interaction of health and financial status in old age.

Applicants may address several areas or themes. These areas are not intended to be prescriptive. Wherever possible special attention should be given to the demographic and economic aspects of the health and well-being of special older populations such as the oldest old, Blacks and Hispanics, and older women.

In addition to (A) an administrative and research support core and (B) a program development core, both of which are required, each proposed Center may request funding for (C) an external innovative network core and/or (D) an external research resources support and dissemination core. Applications are not required to include requests for cores C and D. The following limitations apply to the maximum amount that may be requested for average annual direct costs over five years, excluding the indirect costs associated with consortiums: core A, up to \$160,000; core B, up to \$80,000; core C, up to \$35,000, and core D, up to \$100,000.

Applicants are also encouraged to compete for the coordinating Center function. The coordinating Center will serve to encourage collaboration and net-working among the NIA Demography Centers, arrange annual meetings and produce bibliographic or other special reports. Funds of up to \$25,000 in direct costs (plus indirect costs) may be separately requested for these functions above the \$350,000 total cost limit.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 1, 1994, a letter of intent that includes the number and title of this RFA, a descriptive title, and identification of the Principal Investigator, other key personnel and participating institutions. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIA staff to estimate the potential review workload and to avoid possible conflicts of interests in the review. The letter of intent is to be sent to Dr. Suzman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are advised to discuss their eligibility and project with NIA program staff (listed under INQUIRIES) as early as possible in advance of formal submission. For institutions receiving support from NICHD for Population Centers, the functions and scope of the proposed NIA Aging Center must be clearly differentiated.

All applications must be complete and submitted using form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research or may be obtained from the Office of Grant Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. To identify the application as a response to this RFA, check "YES" in item 2a on the face page of the application and enter the title "Centers on Demography of Aging" and the RFA number. Supplemental instructions for preparing the application are provided in the RFA. Additional instructions for completing an NIA multicomponent application can be obtained from Dr. Suzman at the addresses listed under INQUIRIES.

Send the completed application and three legible copies in a single package, making sure that the original application with the RFA label attached is on top, to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Send two additional copies of the application to:

Michael Oxman, Ph.D.
Scientific Review Office
National Institute on Aging
Gateway Building, Suite 2C212
7201 Wisconsin Avenue
Bethesda, MD 20892

Applications must be received by the Division of Research Grants on March 31, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIA staff for completeness and responsiveness to the RFA. Incomplete or nonresponsive applications will be returned to the applicant without further consideration. Applications may be triaged by an NIA peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review by a special study section convened by the NIA in accordance with the criteria stated below. The second level review will be provided by the National Advisory Council on Aging.

In addition to the general review criteria of scientific and technical merit and the potential for meeting the goals of the RFA, special review criteria are listed in the RFA.

AWARD CRITERIA

The anticipated date of award is September 30, 1994. In addition to the scientific and technical merit of the application, NIA will consider how well the application meets the goals and objectives of the program as described in this RFA, including increasing the number of NIH-funded population centers, as well as the general criteria for excellence, and availability of funds.

Applications recommended for further consideration by the National Advisory Council on Aging will be considered for funding on the basis of overall scientific, clinical, and technical merit of the proposal as determined by peer review, appropriateness of budget estimates, program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct inquiries regarding programmatic issues to:

Dr. Richard Suzman
Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Suite 533
Bethesda, MD 20892
Telephone: (301) 496-3136
FAX: (301) 402-0051
E-mail: Suzman@NIHNIAGW.BITNET

Direct inquiries regarding fiscal matters to:

Ms. Linda Whipp
Grants and Contracts Management
National Institute on Aging
Gateway Building, Room 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472
FAX: (301) 402-3672

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TISSUE AND BIOLOGICAL FLUIDS BANKS OF HIV-RELATED MALIGNANCIES

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFA AVAILABLE: CA-94-003

P.T. 34; K.W. 0715008, 0715035, 0780005

National Cancer Institute

Letter of Intent Receipt Date: April 15, 1994
Application Receipt Date: May 17, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Cancer Therapy Evaluation Program (CTEP) of the Division of Cancer Treatment (DCT), National Cancer Institute (NCI) invites applications from consortia of institutions for cooperative agreements to design and develop banks of tissue and biological fluids and clinical data from patients with HIV-associated malignancies. The purpose of the proposed awards is to stimulate cooperative efforts to identify and improve access to tumor tissue, biological specimens and associated clinical outcome data that could then be utilized for research by the research community at-large on the pathogenesis of HIV-associated malignancies and development of more effective therapies. Seed money can be requested (as described below) for proposed pilot studies utilizing these materials.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Tissue and Biological Fluids Banks of HIV-Related Malignancies, is related to the priority area of cancer and AIDS. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and Canadian for-profit and non-profit organizations, public and private such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government are eligible to apply. Foreign institutions other than Canadian are not eligible to apply or be a collaborating institution. Canadian institutions are included because many of them are members of the NCI-Sponsored Clinical Trials Cooperative Groups and the NIAID-Sponsored AIDS Clinical Treatment Units. Applications must be from a consortium of no less than two institutions, which can include, but are not limited to, the NCI-Sponsored Clinical Trials Cooperative Groups, the NIAID-Sponsored AIDS Clinical Treatment Units, or a coalition of Cancer Centers. New and experienced investigators are encouraged to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be the cooperative agreement (U01), an assistance mechanism, in which substantial NCI scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under the cooperative agreement, the NCI purpose is to support and/or stimulate

the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreement(s) are discussed in the RFA under the section "Terms and Conditions of Award."

Awards and level of support depend on receipt of a sufficient number of applications of high scientific merit. Because of the variation in numbers of patients to be accrued, and specimens to be accessed, it is anticipated that the size of awards will vary also. The total project period for applications submitted in response to the RFA may not exceed four years. The anticipated award date is September 30, 1994. Although this program is provided for in the financial plans of the NCI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

This RFA is a one-time solicitation. At this time the NCI has not determined whether or how this solicitation will be continued beyond the present RFA. If it is determined that there is a sufficient continuing program need, the NCI will either invite recipients of awards under this RFA to submit competitive continuation cooperative agreement applications for review or re-issue the RFA for re-competition. If the NCI does not continue the program, awardees may submit grant applications through the usual investigator-initiated grants program.

FUNDS AVAILABLE

Approximately \$2,000,000 in total costs per year for four years will be committed to fund applications submitted in response to this RFA. It is anticipated that three to four awards for the Tissue and Biological Fluids Banks of HIV-Related Malignancies will be made. Up to ten percent of the total costs, or \$50,000 per year for three years (whichever number is smaller, and to start in year two of the cooperative agreement) can be requested for pilot studies.

RESEARCH OBJECTIVES

The purpose of the proposed awards is to stimulate cooperative efforts to design and develop Tissue and Biological Fluids Banks of HIV-associated malignancies with associated clinical and outcome data. The Banks would provide critical resources to the research community at-large for research studies to gain insight into the pathogenesis of the malignancies that arise in HIV-infected individuals.

Formation of a consortium of institutions is encouraged to maximize specimen accession. All applicants must provide evidence of availability and access to patient specimens, and each Consortium (made up of a minimum of two institutions) must have an Operations Office that is capable of providing the necessary coordination of specimen collection, data management, and storage of specimens at a central location. Banked specimens may consist of fixed or frozen tumor tissue and biological fluids. Investigators must address coordination of quality control among collaborating institutions and consortia with regard to collection, shipment and storage of specimens.

The awardees will provide to the research community at-large tissue and biological fluids of high quality from patients with HIV-associated malignancies for high priority research studies. This task will be accomplished through the workings of two committees, the Steering Committee and the Research Evaluation and Decision Panel (REDP). The duties of these two committees are described in the RFA under SPECIAL REQUIREMENTS.

Of the funds provided by this RFA, at least 90 percent of the total costs proposed in each application must be directed to the actual banking (accession of tissues and biological fluids, facilities, laboratory personnel, clinical data collection and linkage to specimens) and up to 10 percent of the total costs, or \$50,000 per year for three years (whichever number is smaller, to start in year 2 of the cooperative agreement) can be requested for pilot studies. Pilot studies should be designed to obtain sufficient data to form the foundation for future R01 research grant applications. The pilot studies should also help identify new research areas where additional investigations should be pursued. Examples of such studies could include, but are not limited to, the following: prospectively comparing the response to therapy in patients with different molecular characteristics, determining the cytokine expression that might be etiologically involved in the development of the malignancies seen in HIV infection, and the effect on such expression by therapy; evaluating the interaction of other factors with HIV in malignancies, and the effects of therapy on those factors; assessing the impact of therapy both on viral burden and on tumor response, and designing assays for in vitro or in vivo animal models for testing of pharmacologic compounds in HIV-associated malignancies, that could be tested in the context of a clinical trial.

SPECIAL REQUIREMENTS

The RFA describes the complete terms for this cooperative agreement including definitions, terms and conditions of award, responsibilities of the awardees, responsibilities of NCI staff, collaborative responsibilities and the arbitration process to resolve disputes. The RFA is available from the Program Director listed under INQUIRIES.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 15, 1994, a letter of intent that includes a descriptive title of the proposed research, name, address, and telephone number of the Principal Investigator, identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. This letter of intent is not required, is not binding, and does not enter into the review of subsequent applications.

The letter of intent is to be sent to:

Dr. Roy S. Wu
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

APPLICATION PROCEDURES

Applications must be received by May 17, 1994. If an application is received after that date, it will be returned. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NCI Program Director listed under INQUIRIES.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Applications that are judged non-responsive will be returned to the applicant by the NCI. Questions concerning the responsiveness of proposed research to the RFA are to be directed to program staff listed under INQUIRIES.

AWARD CRITERIA

The anticipated date of award is September 30, 1994. In addition to the scientific and technical merit of the application, NCI will consider how well the applicant institution met the goals and objectives of the program as described in the RFA, availability of resources, and study population.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct inquiries regarding scientific issues and requests for the RFA to:

Ellen Feigal, M.D.
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Suite 741
Bethesda, MD 20892
Telephone: (301) 496-2522
FAX: (301) 402-0557

Direct inquiries regarding fiscal matter to:

Ms Carolyn Mason
Grants Management Branch
National Cancer Institute
Executive Plaza South, Room 242
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 59
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV Sections 301, 410, and 411, Part A (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grants policies and Federal Regulation at 42 CFR Part 52, 45 CFR Part 74 and 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems agency review.

DIABETES INTERDISCIPLINARY RESEARCH PROGRAMS

NIH GUIDE, Volume 23, Number 2, January 14, 1994

RFA AVAILABLE: DK-94-017

P.T. 34; K.W. 0715075, 0710030, 1002004, 1002008, 0710070, 1013004

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: June 16, 1994

Application Receipt Date: July 14, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Allergy and Infectious Diseases (NIAID) and the Juvenile Diabetes Foundation International (JDFI) invite investigator-initiated program project grant applications. These applications should incorporate an interdisciplinary research approach: (1) to the development of innovative prevention and treatment strategies for IDDM, (2) to the etiology and pathogenesis of insulin-dependent diabetes mellitus (IDDM) and its complications, and (3) to the genetic susceptibility for IDDM and the complications of diabetes. This solicitation is intended to stimulate the application of advances in basic molecular biology, genetics, immunology, cell biology and biophysics to the study of IDDM and its complications.

Applications will be submitted to the NIH and will be reviewed by NIH according to usual NIH peer review procedures. Applications judged meritorious but not funded by the NIH may be considered by the JDFI for possible funding. Applicants wishing to have their application considered by the JDFI must authorize the NIH to provide a copy of their letter of intent, application, and NIH-prepared summary statement of the initial review to the JDFI.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Diabetes Interdisciplinary Research Programs, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, whether public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

The mechanism of support will be the NIH program project grant (P01) award. A program project grant is for the support of a broadly-based multidisciplinary or multifaceted research program which has a specific major objective or central theme. The award may support research components and core functions. Collectively, these components should demonstrate essential elements of unity and interdependence and result in a greater contribution to program goals than if each activity were pursued individually.

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the principal investigator. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation for applications for new awards. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The total requested project period for applications submitted in response to this RFA may not exceed five years. The earliest possible award date will be April 1, 1995.

FUNDS AVAILABLE

For FY 1995, the NIDDK will commit \$1.5 million and the NIAID will commit \$250,000 to fund applications submitted in response to this RFA. It is anticipated that two to three awards will be made by the NIH. The JDFI plans to make three awards. However, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIDDK and the NIAID, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

The maximum dollar request is limited to \$750,000 in direct costs for the initial budget period. The maximum dollar request is limited to \$3.75 million in direct costs (approximately \$5 million in total costs) for the five-year budget period.

With respect to post-award administration, the current policies and requirements that govern the research grant programs of the NIH or the JDFI will prevail depending on the funding source. Applicants should note that grants funded by the JDFI will be subject to the indirect cost policy of JDFI.

RESEARCH OBJECTIVES

It is the intention of the NIDDK, the NIAID and JDFI to further stimulate the integration of the most current basic biomedical research approaches into diabetes-related research. It is expected that this will be accomplished by bringing to the diabetes arena those who are skilled in these approaches by the support of meritorious, synergistic, multidisciplinary research program project applications. Applications should include the involvement of both basic and applied scientists in collaborative endeavors. The JDFI will NOT consider studies aimed at primary prevention for this particular RFA. Research applications should be in the broad areas of IDDM or molecular and genetic aspects of complications of the disease.

SPECIAL REQUIREMENTS

Applicants should submit a brief letter to the NIDDK indicating whether or not they wish their application to be considered for funding by the JDFI. While applicants may request that their applications be considered only by the NIH and not by the JDFI, it is necessary that the record indicate the applicant's consideration of this opportunity. For those applicants who wish to have the JDFI consider their applications, all materials relating to the applications will be promptly forwarded to that organization, and the summary statements for such applications will be shared with the JDFI when available. The NIDDK will provide no information to the JDFI related to applications from applicants who request that the JDFI not consider their application. Letters of authorization should be prepared by the Principal Investigator and co-signed by the official signing for the applicant organization. This letter may be combined with the Letter of Intent or submitted as a cover letter accompanying the application.

In all cases, the NIDDK and the NIAID will make its funding decisions prior to those of the JDFI.

STUDY POPULATIONS

It is NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them. The study design must seek to identify any pertinent gender or minority population differences.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 16, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent should be sent to:

Dr. Robert D. Hammond
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) must be used in applying for these grants. The form is available from most institutional business offices or from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248. The RFA label available in the 9/91 revision of PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications which are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDDK in accordance with the usual NIH peer review procedures. Following review, the applications will be given a secondary review by the NIDDK Advisory Council and the NIAID Advisory Council unless not recommended for further consideration by the initial review group. Applications which are incomplete or unresponsive to the RFA will be returned to the applicant or held until the next regular receipt date and reviewed by the Division of Research Grants.

INQUIRIES

It is imperative that prospective applicants obtain the RFA before developing their applications. Written and telephone inquiries concerning this RFA are encouraged.

The RFA may be obtained from and inquiries regarding programmatic issues should be directed to:

Joan T. Harmon, Ph.D.
Diabetes Research Section
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 622
Bethesda, MD 20892
Telephone: (301) 594-7565
FAX: (301) 594-9011

Elaine Collier, M.D.
Autoimmunity Section
National Institute of Allergy Infectious Diseases
Solar Building, Room 4A20
Bethesda, MD 20892
Telephone: (301) 496-7985
FAX: (301) 402-2571

Inquiries regarding fiscal matters should be directed to:

Betty E. Bailey
Division of Extramural Activities
National Institute Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7594

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847 and 93.855. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

EDUCATIONAL INTERVENTION RESEARCH ON CANCER RISK REDUCTION FOR HIGH-RISK YOUTH

NIH GUIDE, Volume 23, Number 2, January 14, 1994

PA NUMBER: PA-94-027

P.T. 34, AA; K.W. 0715035, 0502017 0411005

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) invites applications for studies to develop, evaluate, and disseminate effective cancer risk reduction methods and materials for high-risk youth. This population is here defined as children or adolescents aged 1 to 18 years who are from low socioeconomic status households or communities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Educational Intervention Research on Cancer Risk Reduction for High-Risk Youth, is related to the priority areas of tobacco, nutrition, alcohol, HIV infection, and general cancer prevention. Applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, non-profit and for-profit organizations and by public and private entities such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

Grant mechanisms include Research Project Grants (R01); and FIRST (R29) awards. Awards will be administered under the PHS grants policy as stated in the PHS Grants Policy Statement. It is anticipated that size of awards will vary based on nature and scope of proposed research.

It is estimated that more than 20 percent of all American children under 18 years of age live in poverty. Included in this group are approximately 15 percent of all White children, 40 percent of all Hispanic children, and 45 percent of all Black children. These young people are extremely vulnerable to several cancer causing behaviors. Children of poverty often experiment with or are regular users of tobacco or alcohol, are sexually active without the benefits of barrier protection, and have nutritional habits that are unhealthy. Many of these young people live in a world where adult guidance is inadequate, and where the social and institutional environment challenges rather than nurtures development. From a public health perspective, the effects of these conditions are at least two-fold: first, they make programmatic efforts especially difficult to implement, frequently causing impoverished youth to become underserved and hard-to-reach; and second, these conditions predispose children to health-compromising behaviors, thus making them 'high-risk'.

Most experts agree that high-risk youth are typified by several characteristics: they are often economically disadvantaged, the children of substance abuser parents, and/or the victims of physical, sexual, or emotional abuse; they have experienced chronic failure in school or have dropped out of school; and they have had mental health problems, attempted suicide, or committed violent or delinquent acts.

An NCI Expert Advisory Panel considered those youth who are economically disadvantaged, come from dysfunctional families, have little or no parental supervision, have family members or peers who are substance users, have non-substance related deviant behaviors, have low educational achievement and/or aspirations, have experienced chronic school failure or have dropped out of school, or are members of minority or ethnic groups, to be at highest risk and in most need of targeted programs.

While any or all of these characteristics, particularly lack of commitment to education, are important predictors of high-risk behavior, the single most influential antecedent is poverty. Thus, for the purposes of this PA, the following serves as a working definition of high-risk youth: children or adolescents aged 1 to 18 years who are living in low socioeconomic status households or communities. The exact dollar amount of this status is usually determined locally, but may be derived through average income by census tract, high unemployment by census tract, family eligibility for medicaid, eligibility for school breakfast programs or lunch supplements, or as defined in each local jurisdiction.

This PA has two major research objectives related to the high-risk youth population: 1) to develop and conduct educational interventions to reduce cancer risks associated with tobacco use, poor dietary choices, alcohol use, and early, unprotected sexual activity among high-risk youth; and 2) to design and conduct randomized controlled studies among a representative sample of high-risk youth to determine the knowledge, attitude, and behavioral effects of these educational interventions.

Behaviors related to these risk conditions may lead to cancer in several sites. Tobacco use, the single most important and preventable cause of cancer mortality in the U.S., is associated with cancers of the lung, lip, mouth, tongue, pharynx, larynx, esophagus, bladder, kidney, prostate, pancreas, and uterine cervix. More than a third of all cancers in this country may be related to excessive fat consumption and inadequate fiber consumption. Alcohol consumption increases the risk of cancers of the mouth, pharynx, larynx, and esophagus, particularly when combined with smoking. Unprotected sexual activity has been linked to Burkitt's lymphoma (Epstein-Barr virus), cancer of the uterine cervix (herpes simplex type 2 and human papilloma virus), liver cancer (hepatitis B virus), as well as non-Hodgkin's lymphoma and other cancers associated with the AIDS (human immunodeficiency syndrome) virus. These behaviors are changeable, and the cancers associated with them are preventable.

Previous interventions targeted to middle-class populations of youth have been shown to be effective in increasing health knowledge, developing health enhancing attitudes, and causing changes in behavior, particularly when delivered through schools and other community-level organizations. Unfortunately, many poor and underserved children have limited exposure to classroom health education or neighborhood programs. Few studies have demonstrated effective school-based prevention strategies for low-income adolescents, and there is a noticeable lack of proven community interventions that specifically target low socioeconomic populations and ethnic minorities. More research is needed, for instance, on the effects of culturally appropriate intervention models emphasizing cultural pride and history, and the use of ethnically matched staff and peer educators. Also, since clearly not all low socioeconomic status children engage in high risk behaviors, there must be antecedents to risk avoidance. The premise of this PA is that there are factors that predispose, enable, and reinforce health status, that they are identifiable, and that they may be used in a variety of risk reduction interventions for populations of high-risk youth.

Interventions should be based on appropriate behavioral, developmental, and educational scientific theories. They should also be built on the results of previous strategies shown to be efficacious in changing risk factors related to knowledge, attitudes, and behaviors, especially in populations of adolescents. Intervention sites may include community health centers, the juvenile justice system, community youth organizations, or schools. Investigators will be required to give full details of how they intend to accomplish their evaluation, and explain how they will recruit and track what is likely to be a hard-to-reach population. Interventions should use a variety of culturally sensitive approaches rather than a single approach, and should be adapted to the special needs of high-risk youth to provide them with skills to make their own decisions to refrain from unhealthy behaviors in spite of peer, advertising, and other pressures endemic to their social environment.

Projects will consist of intervening and measuring change in a sample drawn from a population of 1 to 18 year olds shown to be of low socioeconomic or other high-risk status by the investigator. Projects will usually include pilot testing survey instruments and techniques for feasibility and acceptability, validating instruments, assessing participation and adherence rates, and adapting materials to cultural sensitivities. Investigators may develop their own, or select from or adapt existing materials or strategies that have been shown to be effective in reducing cancer risks. Techniques for validating effectiveness of methods and materials will also be the responsibility of investigators.

To ensure results that are representative, investigators will be required to randomly assign individuals or groups to treatment and comparison conditions, and to practice the accepted methods of social science and quasi-experimental research. Experimental groups should be matched on socioeconomic status, age, sex, ethnicity, current or past behavioral risk factors, and other relevant variables. Experimental groups must also be of sufficient size to provide the statistical power necessary to detect significant differences between groups on variables of interest.

Both outcome and process evaluations should take place under this PA. While outcome evaluation is justifiably seen as evidence of the degree to which an intervention was successful in helping to ultimately reduce morbidity and mortality, process evaluation should be regarded as equally important in this research because of the need to know more about how to conduct interventions with high-risk populations.

Outcome evaluations should be designed to provide quantitative answers to questions such as: to what degree was tobacco use onset prevented, and tobacco use decreased; to what degree did fruit and vegetable consumption increase, and fat consumption decrease; to what degree was alcohol use onset prevented, and alcohol consumption decreased; to what degree did the age of onset of sexual activity increase, and to what degree did unprotected sexual activity decrease?

Process evaluations should be designed to provide quantitative, and where informative, qualitative answers to questions such as: what are the successful elements of prevention programs for high-risk youth; what are the culturally specific or special needs of these populations, and how can programs be made sensitive to their needs; what role can non-school channels play in reaching these youth; how were community organizations recruited; how were high-risk youth recruited; and to what extent was the program adopted by the institution in which it was implemented?

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

National Institutes of Health (NIH) policy is that applicants for NIH clinical research grants are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear and compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group, together with a rationale for its choice. In addition, gender and racial or ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included on grant application form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial or ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies or etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, applicants must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, review will be deferred until the information is provided.

Peer reviewers will specifically address whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning a priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91) and will be accepted at the standard applications deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 (rev. 9/91) instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The title and number of this PA must be typed on Line 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines be reviewed for scientific and technical merit by study sections of the Division of Research Grants with the usual NIH peer review procedures. Following study section scientific and technical review, the applications will receive a second-level review by an appropriate national advisory council.



3 1496 00575 198

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the MCI. The following will be considered in making funding decisions: (1) quality of the proposed project as determined by peer review; (2) availability of funds; and (3) balance among research topics within the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

D. Michael Anderson, Ph.D., M.P.H.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 232
Bethesda, MD 20892-4200
Telephone: (301) 496-8584

Direct inquiries regarding fiscal matters to:

Victoria Price
Division of Grants Administration
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892-4200
Telephone: (301) 496-7800 ext. 52

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 3
January 21, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NATIONAL RESOURCE CENTER FOR THE PREVENTION OF ALCOHOL, TOBACCO AND OTHER DRUG ABUSE IN WOMEN

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFP AVAILABLE: 277-94-3009

P.T. 34; K.W. 0404009, 0745027

Center for Substance Abuse Prevention

The Center for Substance Abuse Prevention (CSAP) proposes to award a three-year cost-reimbursement, level-of-effort type contract to establish a National Resource Center for the Prevention of Alcohol, Tobacco and Other Drug Abuse in Women. This procurement will assist CSAP to continue the services of the CSAP National Resource Center for the Prevention of Perinatal Abuse of Alcohol and Other Drugs (Lewin Contract No. 277-91-3004). Through the establishment of a CSAP National Resource Center for the Prevention of Alcohol, Tobacco, and Other Drug (ATOD) Abuse in Women, CSAP seeks to expand its effort to provide state-of-the-art information regarding our understanding of the public health issues of women as it relates to ATOD abuse prevention. This contract will assist CSAP in achieving its mission by serving as the Nation's focal point for policy orientation, disseminating new research information, information and referral services, training services, systems design, technical assistance, and evaluation findings for programs targeting ATOD abuse prevention in women, including pregnant and parenting women, their children, female adolescents, and women in life crisis at risk of ATOD abuse, including prescription drugs. The CSAP National Resource Center for the Prevention of Alcohol, Tobacco and Other Drug Abuse in Women has four main objectives: (1) study and develop programs relevant to the prevention, intervention, and follow-up of substance use in the target population; (2) maintain a network of experts to serve as an information source; (3) provide training experiences for interdisciplinary teams; and (4) maintain a data base for monitoring and evaluating the activities of the CSAP National Resource Center. Services to be provided under this procurement include: the promotion of the CSAP National Resource Center's services, information technology systems and services; national conferences, issue fora, resource packages, a report on the field, community team training institutes, a national information and referral service, and special disciplinary training programs. It is estimated that 36 months will be required for this project. However, two separate one-year extension options are also included; if both are exercised the contract will be of five years duration. In addition, a third option is included to increase the number of interdisciplinary teams trained.

INQUIRIES

This is an announcement for an anticipated Request for Proposal (RFP). RFP No. 277-94-3009 will be available approximately January 31, 1994, with a closing date tentatively set for March 31, 1994. Request for the RFP along with two self-addressed labels must be submitted in writing to:

Catherine Kellington
Contracts Management Branch
Center for Substance Abuse Prevention
5600 Fishers Lane
Rockwall II Building, Room 670
Rockville, MD 20857

NATIONAL CLEARINGHOUSE FOR ALCOHOL AND DRUG INFORMATION

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFP AVAILABLE: 277-94-4010

P.T. 34; K.W. 0404009, 0745027

Center for Substance Abuse Prevention

The Center for Substance Abuse Prevention (CSAP) has a requirement for the operation of the National Clearinghouse for Alcohol and Drug Information (NCADI). This is an unrestricted recompetition of a current contract with Social and Health Services, Ltd., Rockville, Maryland. The Clearinghouse facilities shall be separately identified headquarters site and warehouse. NCADI's specific purpose is to collect, analyze, process, synthesize, prepare, promote, and disseminate prevention, intervention, and treatment information on alcohol, tobacco, and other drugs (ATOD) and other cross-cutting issues (e.g., HIV/AIDS, violence, child abuse), to a wide array of customers, including parents, the elderly, law enforcement officers, teachers, doctors, reporters, and others. The contractor will be required to maintain the clearinghouse to ensure the widespread dissemination of such information. To achieve this purpose, the contractor will also work with a broad array of intermediaries, including the Regional Alcohol and Drug Awareness Resource (RADAR) Network, and will disseminate information to scientists, policy makers, planners, practitioners, educators, health care providers, the media, and the general public to ensure full public access to free and at-cost information on ATOD use and effective approaches to reducing ATOD-related problems in the United States. NCADI is also the single point of entry for a network of all the Federal alcohol and drug clearinghouses, known as the "Federal Drug, Alcohol, and Crime Clearinghouse Network," established by the Office of National Drug Control Policy (ONDCP) in cooperation with the Department of Health and Human Services, the Department of Justice, the Department of Housing and Urban Development, and the Department of Education. It is anticipated that one contract award will be made under this RFP for a four-year period with a one-year option for continuation as well as other options.

INQUIRIES

This is an announcement for an anticipated Request for Proposal (RFP). RFP No. 277-94-4010 will be available approximately January 21, 1994, with a closing date tentatively set for March 21, 1994. Requests for the RFP along with two self-addressed labels must be submitted in writing to:

Mary Anne Glitz
Contracts Management Branch
Center for Substance Abuse Prevention
5600 Fishers Lane
Rockwall II Building, Room 670
Rockville, MD 20857

OPERATION AND MAINTENANCE OF THE DTP BIOLOGICAL DATA PROCESSING SYSTEM

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFP AVAILABLE: NCI-CM-57198-12

P.T. 34; K.W. 0780018, 0715035

National Cancer Institute

The Developmental Therapeutics Program (DTP), Information Technology Branch, Division of Cancer Treatment (DCP), National Cancer Institute (NCI), is seeking an organization to provide support for DTP's Biological Data Processing System. This system provides laboratory microcomputer support and large-scale database management for the NCI's anticancer and anti-AIDS drug discovery activities, which include the annual in vitro screening of many thousands of synthetic compounds and natural product extracts. The contractor will be responsible for the current Biological Data Processing system and all of its subsystems. This responsibility will include design and/or redesign of system programs as well as initial coding, revising, testing, debugging, documentation, operation, and/or maintenance of all system software. The contractor will also provide support for installation and operation of the systems and development of new hardware/software systems as required for further development of the DTP drug discovery and development programs. It is anticipated that a single, incrementally funded, level-of-effort contract award will be made for a five-year period of performance. Offerors will be invited to submit proposals in conformance with the Government's requirement of 12,750 direct labor hours per year (63,750 total direct labor hours required). This is a recompetition of contract N01-CM-07353 currently performed by Capital Technology and Information Services, Inc.

INQUIRIES

RFP No. NCI-CM-57198-12 will be issued on or about January 20, 1994 and proposals will be due approximately March 4, 1994. Copies of the RFP may be obtained by sending a written request to:

Ms. Joyce A. Crooke
Research Contracts Branch, TCS
National Cancer Institute
Executive Plaza South, Room 603
Bethesda, MD 20892
Telephone: (301) 496-8620

No collect calls will be accepted.

PRECLINICAL PHARMACOLOGICAL STUDIES OF ANTITUMOR AND ANTI-HIV AGENTS

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFP AVAILABLE: NCI-CM-57199-12

P.T. 34; K.W. 0710100, 0740020

National Cancer Institute

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment, is soliciting organizations having the necessary experience, scientific and technical personnel, and facilities to conduct a series of preclinical pharmacokinetic and other pharmacology studies in non-disease bearing animals on agents having demonstrated antitumor or anti-HIV activity and considered by DCT to merit further development. The studies to be performed will include: the development of methodology for the quantitative measurement of test agents and/or metabolites in animal body fluids and tissues; stability studies of test agents in biological fluids; plasma protein binding determinations; characterization of in vivo plasma concentration-time profiles and calculation of relevant pharmacokinetic parameters; determination of test agent levels in samples provided by other DTP contractors; determination of the most effective mode of agent administration to achieve and maintain effective concentrations in body fluids and tissues; bioavailability studies following administration of an agent by various routes; tissue distribution and urinary excretion studies; structural determination of metabolites and/or degradation products of parent agents produced in animals and in model in vitro systems (e.g., animal and/or human liver slices, S9 fractions, and microsomal preparations). Where appropriate, this information will be related to mechanisms of antitumor or antiviral action. The Government will supply all animals (mice, rats, dogs, non-human primates), test agents, and radiolabeled test agents. Contractors will be expected to provide all equipment, solvents, reagents and animal facilities needed to conduct this type of work. AAALAC accreditation is highly desirable and is required by time of award. It is anticipated that four to five awards will be made as a result of the Request for Proposal (RFP), each for a three to five year, incrementally-funded level-of-effort contract. Only one award will be made to an institution. The following Mandatory Qualification Criteria will apply: (1) the Contractor may not be a pharmaceutical or chemical firm since agents of a commercially confidential nature (discreet) may be evaluated; (2) since structural formulas and other information on discreet agents may be included in a Task Order

Request, contractors must be willing to sign a confidentiality of information statement; (3) the Contractor must possess a valid NRC license permitting the purchase, storage, and use of typical quantities of radioisotopes (e.g., ³H, ¹⁴C, ³⁵S) likely to be used in the proposed pharmacological research.

INQUIRIES

RFP No. NCI-CN-57199-12 will be issued on or about January 18, 1994 and proposals will be due approximately March 4, 1994. Copies of the RFP may be obtained by sending a written request to:

Ms. Joyce A. Crooke
Research Contracts Branch, TCS
National Cancer Institute
Executive Plaza South, Room 603
Bethesda, MD 20892
Telephone: (301) 496-8620

No collect calls will be accepted.

EVALUATION OF CHEMOPREVENTIVE AGENTS BY IN VITRO TECHNIQUES

NIH GUIDE, Volume 23, Number 3, January 21, 1994

MAA AVAILABLE: NCI-CN-45581-70

P.T. 34; K.W. 0715035, 0740018, 0755010

National Cancer Institute

The Chemoprevention Branch, Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), in its annual requirement to seek new sources, is soliciting proposals for the Evaluation of Chemopreventive Agents by In Vitro Techniques to increase the number of Master Agreement (MA) Holders. Current MA Holders for this program are not required to submit a proposal. This Master Agreement Announcement (MAA) is issued to solicit MA Holders who have adequate capabilities and technical expertise to screen and evaluate the activity of chemopreventive agents in various in vitro assays of cell transformation. Agents with potential chemopreventive activity are identified by epidemiologic surveys, initial laboratory (experimental) findings, observations in the clinical setting, or structural homology with agents having known chemopreventive activity. A rigorous and systematic evaluation of these candidate agents is necessary before their efficacy can be examined in clinical trials for cancer prevention. In vitro screening and evaluation techniques measuring the ability of these chemopreventive agents to inhibit transformation provides a relatively rapid and efficient means of qualifying these agents for further evaluation for the prevention of cancer in humans. Agents to be investigated by this project are potentially hazardous. The in vitro systems may involve the use of carcinogens, tumor cells, or tumor viruses. Laboratory practices will be employed, which will keep any element of risk to personnel at an absolute minimum. Where indicated, tissue and compound handling must be performed in (at least) Class I laminar flow cabinets that must meet NIH specifications for work with these agents. The offeror will comply with NCI safety standards for research involving chemical carcinogens (DHHS Publication No. NIH 76-900 and the FDA Good Laboratory Practices Regulations). It will be required that the facilities have operating tissue culture/cell biology and chemistry laboratories that are suitable for using hazardous and/or carcinogenic materials as test materials. The contractor must have or be able to obtain all equipment necessary to accomplish the studies including but not limited to, laminar flow hoods, CO₂ incubators, equipment for sterility testing, isotope counters, spectrophotometer, hazardous chemical storage cabinets and refrigerators, equipment such as microscopes and miscellaneous laboratory equipment. The laboratory will have or have access to appropriate terminal and computer facilities and equipment for data collection and storage. The period of performance of the MA pool will be three years. It is estimated that up to four Master Agreement Orders per year will be issued pursuant to the Master Agreements.

INQUIRIES

Requests for this solicitation must be in writing and reference MAA No. NCI-CN-45581-70. The MAA will be available approximately January 24, 1994 and due approximately February 24, 1994. Requests are to be addressed to:

Ms. Erin C. Lange
Research Contracts Branch, PCCS
National Cancer Institute
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

THE IMPACT AND COSTS OF SEALANTS IN YOUNG CHILD POPULATIONS

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFP AVAILABLE: NIH-NIDR-1-94-2R

P.T. 34; K.W. 0745010, 0745027

National Institute of Dental Research

The National Institute of Dental Research (NIDR) has a requirement for the development and implementation of a randomized experimental study of the value (cost and outcomes) of dental sealants. The study design will allow for three experimental payment systems (e.g., different mix of services covered) and a comparison representing existing payment systems across two socioeconomic strata. The design will incorporate the existing dental care delivery system in the proposed sites. The active stage of the experiment will last three years (dental payment plans in effect). Participants in the experimental groups will receive information about a dental payment plan. Designated services in the payment

plan will be paid for by the contractor during the three years of the experiment. Analyses will include comparative trends over time in dental caries, restorations, dental sealant use/retention and other measures of oral status, services rendered, cost of care, and oral health behaviors. Outcomes to be assessed will include both differences in rates of decay and the financial investment. The outcome will be the return on investment, if any, in terms of level of health and dollars expended to cover the cost of dental sealants in a dental benefits package.

INQUIRIES

RFP No. NIH-NIDR-1-94-2R will be available on or about January 21, 1994, with proposals due on March 30, 1994. Requests for the RFP must be submitted in writing and addressed to:

Marion L. Blevins
Contracts Management Office
National Institute of Dental Research
Westwood Building, Room 533
Bethesda, MD 20892

EARLY CELLULAR RESPONSE TO INJURY OF THE VESTIBULAR SYSTEM

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFA AVAILABLE: DC-94-001

National Institute on Deafness and Other Communication Disorders

Letter of Intent Receipt Date: February 14, 1994

Application Receipt Date: March 29, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH) invites grant applications for the support of basic studies on the molecular and cellular mechanisms subserving the early recovery process following injury to the mammalian vestibular system. An understanding of the mechanisms of this recovery will likely provide important insight into pharmacotherapeutics of vestibular disorders in humans.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Early Cellular Response to Injury of the Vestibular System, is related to the priority areas of Physical Activity Fitness, Unintentional Injuries, Diabetes and Chronic Disabling Diseases and Clinical Prevention Services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-1147 3-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Domestic applications may include international components. Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

FUNDS AVAILABLE

It is expected that \$750,000 will be available for the first year of support (direct cost) for the entire program and that up to three applications will be funded. The level of support is dependent on the scientific merit and scope of the applications and the availability of funds.

RESEARCH OBJECTIVES

This initiative seeks to establish the molecular and cellular mechanisms and sites of action in the vestibular nuclear complex (VNC) and in the central vestibular circuits that follow injury of the vestibular endorgan and/or the vestibular nerve in mammalian experimental animal models. An understanding of these mechanisms will likely provide important insight into the design of pharmacotherapeutic agents that will initiate and/or accelerate the compensation process in vestibular-disordered patients.

There is an urgent need for a concentrated research effort to identify the neurotransmitter, neuromodulator and second messenger substrates involved in normal vestibular function that may change during the process of neurogenic recovery underlying vestibular compensation.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 14, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDCD staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Scientific Review Branch
National Institute on Deafness and Other Communication Disorders
Room 400-B, Executive Plaza South
6120 Executive Boulevard
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NIH program administrator listed under INQUIRIES.

Applications must be received by March 29, 1994. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIDCD staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIDCD staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

AWARD CRITERIA

The anticipated date of award is July 1, 1994.

An award will be made on the basis of assessment of the applications by peer review, considerations of programmatic balance, and the appropriation of allocated funds for this RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Daniel A. Sklare, Ph.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-C
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-1804
FAX: (301) 402-6251

Direct inquiries regarding fiscal matters to:

Sharon Hunt
Division of Extramural Activities
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-B
6120 Executive Blvd.
Bethesda, MD 20892
Telephone: (301) 402-0909
FAX: (301) 402-1758

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFA AVAILABLE: DA-94-003

P.T. 34; K.W. 0404001, 1002030, 0710085, 0755030, 0705010

National Institute on Drug Abuse

Letter of Intent Receipt Date: March 12, 1994

Application Receipt Date: April 12, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

A generation of neuroscientific research utilizing animal models has provided the identification of receptors for every major abused drug and many of their endogenous ligands. A variety of models have been developed to explain the fundamental behavioral and biological mechanisms of addiction, e.g., brain reward, tolerance, and dependence. These discoveries and models, coupled with the rapid advances in noninvasive brain imaging methodology, now make it feasible to study drug addiction and the human brain to determine the etiology and the biomedical and biobehavioral consequences of drug abuse, as well as the effects of treatment of this disorder. The NIDA proposes to initiate a major program using noninvasive technologies or autopsy materials to study the human brain and the etiology and consequences of drug abuse and to translate this information into novel prevention, diagnostic, and treatment strategies. Research grant applications to use current, or to develop new, noninvasive techniques to assess neuroanatomical, neurochemical, or other functional differences or changes in human brain that contribute to vulnerability to drug abuse, are a consequence of drug use, or result from pharmacological or non-pharmacological treatment are therefore invited. These applications may establish integrated, multidisciplinary imaging programs in which basic and clinical studies are conducted in humans, or the application may request support for smaller studies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Human Basic and Clinical Neuroscience of Drug Addiction, is related to the priority areas of tobacco, alcohol and other drugs, and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit, public and private organizations, e.g., colleges, universities, hospitals, laboratories, units of State and local government, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible for the program project (P01) or center grant (P50) awards.

MECHANISMS OF SUPPORT

Support mechanisms include research project grants (R01), program projects (P01), center grants (P50), and small grants (R03). Investigators may also respond to this RFA under the Interactive Research Project Grant Program (IRPG). If an investigator wishes to respond under an IRPG, additional requirements must be met as described in PA-93-078. However, if the IRPG mechanism is used under this RFA, this RFA deadline receipt date takes precedent over the IRPG special receipt date. Most investigator-initiated research is supported by research project grants (R01). Research grants are awarded to institutions on behalf of Principal Investigators who have designed and will direct a specific project or set of projects. Research project grants can be renewed at intervals or supplemented through the formal submission and review process described below. Investigator(s) may apply for a renewal (competing continuation) of R01 grants by submitting an application for further support, including a report of progress and including specific plans for future work. Applications for competing supplements to expand the scope of ongoing grants that utilize the R01, P01, or P50 mechanism to include human neuroscience may be submitted.

FUNDS AVAILABLE

It is anticipated that approximately \$10 million will be available to support the first year of the human neuroscience research program. Because the nature and scope of the research proposed in response to this RFA may vary, the size of an award will vary also. However, it is anticipated that approximately 20 new awards will be made under this announcement.

RESEARCH OBJECTIVES

This research program is intended to support (1) individual research project grants on basic and clinical human neuroscience and (2) the establishment of human neuroscience research centers (HNRCs) to conduct interdisciplinary research on the human neuroscience of drug addiction. Research using animals is not excluded but their use in projects submitted under this RFA must be specifically justified. Effort is to be made to use state-of-the-science approaches.

Human neuroscience research within an HNRC should involve the systematic development and integration of knowledge derived from a variety of sources, and should utilize a number of designs. The proposed research must be organized around a central theme. The theme of the HNRC should clearly relate to investigating the human neuroscience of drug addiction.

SPECIAL REQUIREMENTS

There are special requirements for the center grant (P50), program project (P01), and small grant (R03) applications. If an applicant intends to apply under this RFA utilizing either of those support mechanisms, they may contact the program person listed under INQUIRIES for further information.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations of clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 12, 1994, a letter of intent that includes a descriptive title of the proposed research, the proposed mechanism, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that is contained allows NIDA staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Director, Office of Extramural Program Review
5600 Fishers Lane, Room 10-42
Rockville, MD 20857
Telephone: (301) 443-2755

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301-594-7248.

Applications must be received by April 12, 1994.

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary DHHS grant programs. Applications received under this RFA will be assigned to a special review group convened by NIDA. Pre-review site visits will not be made, and applications may not be deferred for site visit; therefore, applications must be complete when submitted.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA and special instructions, and inquiries regarding programmatic issues to:

Christine R. Hartel, Ph.D.
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-31
Rockville, MD 20857
Telephone: (301) 443-1887

Direct inquiries regarding fiscal or grants management issues to:

Gary Fleming, J.D., M.A.
Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalogue of Federal Domestic Assistance No. 93.279. Awards are made under authorization of the Public Health Service Act, Section 301, and administered under PHS grants policies and Federal Regulations at Title 42 CFR 52 "Grants for Research Projects," Title 45 CFR Part 74 & 92, "Administration of Grants" and 45 CFR Part 46, "Protection of Human Subjects." Title 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

INTERSTITIAL CYSTITIS AND OTHER BLADDER DISORDERS OF WOMEN

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFA AVAILABLE: DK-94-012

P.T. 34, II; K.W. 0705075, 0715125, 0715123

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: March 15, 1994

Application Receipt Date: April 26, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Kidney, Urologic, and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in association with the Office of Research in Women's Health (ORWH), Office of the Director, NIH, solicits research grant applications for support of basic and clinical studies focused on the normal and abnormal function of the urinary bladder, specifically as it relates to the urinary bladder disorders of women: interstitial cystitis, urinary tract infections, urinary incontinence, and the basic bladder physiology of women.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Interstitial Cystitis and Other Bladder Disorders of Women, is related to the priority area of chronic debilitating illness. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Minority individuals and women are encouraged to submit as principal investigators.

MECHANISM OF SUPPORT

Support of this program will be through the NIH research project grant (R01) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

This RFA is a one-time solicitation. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. The total requested project period for applications submitted in response to this RFA may not exceed five years. The earliest possible award date will be September 30, 1994.

FUNDS AVAILABLE

For FY 1994, \$2,500,000 will be committed by the NIDDK to fund applications submitted in response to this RFA. It is anticipated that 10 to 15 awards will be made. This funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Applicants must limit their requests to not more than \$160,000 direct costs for the initial budget period. Although this program is provided for in the financial plan of the NIDDK the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this RFA is to solicit applications from basic science and clinical investigators who will collaborate in developing approaches to the study of the urinary bladder and its disorders in women. Included in the scope of this RFA are basic and clinical studies on bladder development, basic bladder physiology, studies of bladder immunology, bladder mucosa and epithelium, comparative studies with other organ systems such as the gut, kidney, etc., especially as related to interstitial cystitis, urinary tract infections and urinary incontinence and basic bladder physiology.

SPECIAL REQUIREMENTS

Applicants who receive an award through this RFA are encouraged to attend a yearly meeting (convened by the NIDDK) of investigators to discuss progress and exchange research information. Funds to support the travel to these meetings should be included in the proposed budget and can be in addition to other proposed travel.

In order to ensure that patient selection for clinical studies is uniform, the NIDDK has established Diagnostic Criteria for research studies on Interstitial Cystitis (IC). All grant applications for research on IC that use human subjects must state that the NIDDK IC Diagnostic Criteria for Research will be applied to patients selected for inclusion in the research study. The NIDDK research criteria have been published in the JOURNAL OF UROLOGY 142(1): 139, 1989 and the AMERICAN JOURNAL OF KIDNEY DISEASES 8(4) 353, 1989.

The Diagnostic Criteria for other urological diseases that are studied must also be defined in the research grant

application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 15, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the names of key personnel and the participating institutions, and the number and title of the RFA in response to which the application may be submitted. The letter is not binding, is not a requirement for submission, and does not enter into the review of the application. The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. The form is available from most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and check the YES box.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At time of submission, two additional copies of the application must also be sent, under separate cover to:

Dr. Robert Hammond
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892

Applications must be received by April 26, 1994. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, it is allowable to submit the same project as both an R01 and as a component project of a program project. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications previously reviewed. Such applications must not only include an introduction addressing the previous critique but also be responsive to this RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Ralph L. Bain, Ph.D.
Division of Kidney, Urologic, and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Disease
Westwood Building, Suite 3A-05
Bethesda, MD 20892
Telephone: (301) 594-7556
FAX: (301) 594-7501

Inquiries regarding fiscal matters may be directed to:

Ms. Trude McCain
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Disease
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

Schedule

Letter of Intent Receipt Date: March 15, 1994
Application Receipt Date: April 26, 1994
Initial Review: June/July 1994
Second Level Review: September 1994
Anticipated Date of Award: September 30, 1994

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849 (NIDDK). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

COOPERATIVE PROGRAM FOR RESEARCH ON DIABETIC RETINOPATHY

NIH GUIDE, Volume 23, Number 3, January 21, 1994

PA NUMBER: PA-94-028

P.T. 34; K.W. 0715080, 1002004, 1002008

National Eye Institute

PURPOSE

The National Eye Institute (NEI) and the Juvenile Diabetes Foundation International (JDFI) have initiated a cooperative program of research support. The purpose of this effort is to stimulate basic cellular and molecular biological research on diabetic retinopathy. Applications submitted to the NIH will be assigned and reviewed according to the usual NIH peer review procedures. Meritorious applications not funded by the NEI may be considered by the JDFI for possible funding.

Although not participating in this specific program, the National Institute of Diabetes and Digestive and Kidney Diseases continues to have a strong interest in the retinal complications of diabetes as indicated by its continuing support of The Diabetes Control and Complications Trial, which has diabetic retinopathy as one of its outcome measures.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Cooperative Program for Research on Diabetic Retinopathy, is related to the priority area of reducing blindness among people with diabetes. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanism of NEI support for this program will be the research project grant (R01) or FIRST (R29) award. The NEI and the JDFI plan to make several awards each in FY 1994 and for several years thereafter. With respect to post-award administration, the current policies and requirements that govern the research grant programs of the NIH and the JDFI will prevail depending on the funding source. Applicants should note that awards made by the JDFI will be subject to the JDFI indirect cost policy.

RESEARCH OBJECTIVES

The purpose of this NEI/JDFI cooperative program is to accelerate basic research activities directed toward discovering the cellular and molecular basis of diabetic retinopathy. Recent advances in structural, cell, and molecular biology can be applied more widely to gain a better understanding of retinal cell basement membrane biology, pericyte-endothelial cell interactions, three-dimensional structure of retinal enzymes, and regulation of retinal gene expression. More information about retinal metabolic pathways and how these pathways are regulated could possibly lead to the development of biological modifiers or pharmacologic agents that would be useful in preventing or treating diabetic retinopathy.

Diabetes can lead to changes in the permeability of the retinal vasculature resulting in retinal edema and blurring of vision. In more advanced cases of diabetic retinopathy, retinal neovascularization can lead to leakage of blood into the retina, retinal detachment, with consequent catastrophic loss of vision. While great strides have been made in the treatment of diabetic retinopathy through such clinical trials as the Diabetic Retinopathy Study, the Early Treatment of Diabetic Retinopathy Study, and the Diabetic Retinopathy Vitrectomy Study, more research is needed on basic cellular and molecular mechanisms of disease.

Studies in experimental animals point to elevated blood glucose levels as important in the pathogenesis of diabetic retinopathy. Laboratory investigations employing cultured cells show that elevated glucose levels affect the metabolism and growth of pericytes, capillary endothelial cells, and retinal pigment epithelial cells. However, the fundamental mechanisms which cause diabetic retinopathy remains unknown. One hypothesis is that increased levels of intracellular sorbitol are generated from glucose via the polyol pathway by the enzyme aldose reductase. Altered sorbitol levels in turn may affect important cellular metabolites such as myoinositol and the functioning of enzymes such as sodium-potassium ATPase. Another hypothesis is that elevated glucose levels activate protein kinase C (PKC) in the retina and may mediate some of the vascular complications of diabetes. A co-culture system of endothelial cells and pericytes has been used to demonstrate that pericytes inhibit growth of capillary endothelial cells, putatively through activation of transforming growth factor beta. Other work has shown that both acidic and basic fibroblast growth factors can stimulate the formation of new blood vessels in vivo. A wide variety of other growth factors have been implicated as possible causal agents of retinal neovascularization. These include growth hormone, insulin-like growth factors, and insulin. Endothelin-1, a potent vasoconstrictor, is secreted by endothelial cells and binds to a high affinity binding site on retinal pericytes. This binding can be decreased by elevated glucose levels. Cultured vascular cells or pericytes exposed to high glucose levels show increased levels of mRNA for collagen IV and fibronectin. However, while there is documented evidence of retinal vascular cell response to high levels of glucose, the fundamental mechanisms that lead to diabetic retinopathy remain to be determined.

SPECIAL REQUIREMENTS

The NEI and the JDFI plan to sponsor periodic meetings to facilitate exchange of information among investigators funded as a result of this initiative and to foster collaborative efforts among investigators. For this purpose, requests for travel funds for a two-day meeting each year, in Bethesda, Maryland, should be included in the budget.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title "Cooperative Program for Research on Diabetic Retinopathy" must be typed in Section 2a on the face page of the application.

Applications for the FIRST award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five exact copies must be mailed or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

LETTER OF AUTHORIZATION

Applicants responding to this program announcement must submit a brief letter as part of the application indicating whether or not they wish their application to be considered for funding by the JDFI. Letters of authorization should be prepared by the Principal Investigator and co-signed by the appropriate official of the applicant organization. Applicants wishing to have their applications considered by the JDFI must specifically authorize the NEI to provide a copy of their application and the NIH-prepared summary statement of the initial review to the JDFI.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by the Initial Review Groups of the Division of Research Grants, NIH, in accordance with the standard peer review procedures. Following initial scientific and technical review, the applications assigned to the NEI will receive a second level review by the National Advisory Eye Council.

AWARD CRITERIA

The following will be considered in making funding decisions on applications assigned to the NEI:

- o scientific and technical merit of the proposed project as determined by peer review,
- o relevance to NEI program priorities as identified in "Vision Research - A National Plan: 1994-1998," and this announcement, and
- o availability of funds.

The NEI will make its funding decisions first. Upon request (see above), those applications not funded by the NEI will be considered for funding by the JDFI. If the JDFI makes an award, the applicant will be notified directly by the JDFI.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding scientific issues to:

Peter A. Dudley, Ph.D.
Retinal Diseases Branch
National Eye Institute
Executive Plaza South, Suite 350
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-0484

Direct inquiries regarding fiscal matters to:

Ms. Margie Baritz
Division of Extramural Activities
National Eye Institute
Executive Plaza South, Suite 350
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-5884

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.867, Vision Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. Applications are not subject to the intergovernmental review requirements of Executive Order 12372 as implemented through Department of Health and Human Services regulations at 45 CFR part 100 or Health Systems Agency review.

HIV, AIDS AND RELATED ILLNESSES COLLABORATION AWARD

NIH GUIDE, Volume 23, Number 3, January 21, 1994

PAR NUMBER: PAR-94-029

P.T. 34, 48; K.W. 0715008

Fogarty International Center

PURPOSE

The Fogarty International Center (FIC) is expanding its AIDS International Research and Training Program to provide small individual research grants for collaboration between U.S. and foreign scientists in any country, consistent with U.S. foreign policy considerations. Support is available for research on human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS), and for research related to AIDS. Up to \$20,000 per year for a maximum of three years is available for U.S. investigators and their foreign collaborators to conduct research mainly at the foreign site. U.S. investigators holding currently active NIH grants for research related to HIV infections, AIDS, and other related health problems are eligible to apply with their foreign collaborator for the AIDS Fogarty International Research Collaboration Award (AIDS-FIRCA).

Grants will provide funds to the foreign collaborator, through the U.S. grantee institution, for supplies at the foreign institution; for expenses incurred at the U.S. institution to support the collaboration; and for research-related travel and subsistence expenses for both the U.S. and foreign investigators. If the foreign collaborator is in a developing country, applicants may also request funds for small pieces of equipment necessary to the AIDS-FIRCA project at the foreign site.

For the purpose of this program, developing countries are considered to include those in the following regions: Africa, Asia (except Hong Kong, Japan, Singapore, South Korea and Taiwan), Central and Eastern Europe, Latin America, the Middle East (except Israel and the Persian Gulf states), and the Pacific Ocean Islands (except Australia and New Zealand).

ELIGIBILITY

To be eligible for the AIDS-FIRCA program, the following conditions must be met:

- o The proposed U.S. Principal Investigator must be the Principal Investigator (Project Director) of an NIH-sponsored AIDS or AIDS-related research grant project (R, P, or U01 series) that will be active and funded during the proposed grant award period (up to three years). Under exceptional circumstances, after consultation with program officials, some research contracts (N01 series) may be eligible "parent" funding for the AIDS-FIRCA. On submission of an application, at least 19 months of active research support must remain on the listed parent grant. Investigators may request the full three years of support in the FIRCA application in cases where less than three future years remain on the parent grant, presuming that the renewal application will be submitted and awarded.
- o The foreign collaborator must hold a position at an institution in a foreign country that will allow him or her adequate time and provide appropriate facilities to conduct the proposed research.
- o The application must demonstrate that the award will enhance the scientific contributions of both the U.S. and foreign scientists and will enhance or expand the contribution of the NIH-sponsored research project (parent grant).

MECHANISM OF SUPPORT

The small grants (R03) will provide up to \$20,000 per year in direct costs for up to three years. Funds may be used for materials and supplies necessary to conduct the collaborative research in the foreign scientist's research laboratory or site, and for costs related to the AIDS-FIRCA project at the U.S. institution. Equipment requests are limited to items for use in the AIDS-FIRCA project at foreign institutions in developing countries.

Travel and subsistence-related expenses may be requested for the U.S. Principal Investigator, the foreign collaborator, and/or their colleagues for visits directly related to the subject of the collaborative research. All proposed expenditures must be well justified and clearly related to the research objectives of the proposed project.

Applicants should request support to conduct research not already being supported by the U.S. investigator's parent grant; however, the research application must be an extension of or related to the research project currently funded by the NIH. The awards will be made to U.S. institutions, which will be responsible for the expenditures. The minimum FIRCA project period will be for one year, the maximum will be for three years, and depends on the continuation of appropriate NIH support of the Principal Investigator's AIDS-related research. If the related NIH research project (parent) grant expires in less than three years' time it may, upon renewal, reestablish eligibility for a continuation of the AIDS-FIRCA award for the full award period. Since the research supported under this award is mainly to occur at the foreign site, indirect costs will be calculated on the basis of the off-site rate of the U.S. sponsoring institution.

RESEARCH OBJECTIVES

The main objective of this AIDS-FIRCA program is to facilitate unique and highly promising collaborative basic and applied research efforts between U.S. and foreign scientists that will both expand and enhance the HIV- and AIDS-related NIH-supported research program of the U.S. Principal Investigator and benefit the scientific interests of the collaborating foreign scientist. All areas of research directly and indirectly related to HIV infection and AIDS are eligible for consideration. Examples of topics include, but are not limited to:

- o Research related to the development of HIV/AIDS vaccines;
- o Research on antiviral and other interventions for HIV/AIDS;
- o Research on HIV and infection by the virus;
- o Research on other retroviruses related to HIV;
- o Studies of maternal/pediatric HIV infections;
- o Cofactors involved in HIV infection;
- o Studies on the spread of HIV infection and AIDS into new locales;
- o The natural history of HIV infection;
- o Research on opportunistic infections and other disorders that result from immunosuppression by the AIDS virus;
- o Studies of emerging/reemerging microbes and diseases linked to factors known or suspected to relate to the spread of HIV; and
- o Research on the social and behavioral factors that affect HIV risk and transmission.

Applicants should be aware that applicable provisions for protection of human research subjects and laboratory animals must be met in both domestic and foreign settings. See Title 45 CFR, Part 46, for information concerning the Department of Health and Human Services regulations for the protection of human subjects and the PHS Policy on Humane Care and Use of Laboratory Animals. These are available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892. Information on these assurances is included in the special application instructions available from FIC (address below).

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided. FIRCA applicants should employ these principles in the design of studies and the selection of subjects or materials relative to the local population, and include a statement indicating the relationship of the design to the U.S. population.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications must be submitted by the U.S. Principal Investigator on standard form PHS 398 (rev. 9/91), which is available from most U.S. institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Bethesda, MD 20892, telephone (301) 594-7248.

Special application instructions are required and are available from FIC program staff listed under INQUIRIES. All budget item requests must be fully justified.

The application consists of a portion to be completed by the U.S. Principal Investigator and a separate portion to be completed by the foreign collaborator. Both portions of this application must be submitted as a single package by the U.S. grantee institution.

Receipt dates for completed applications are October 1, February 1, and June 1. If the deadline falls on a weekend or a holiday, it is automatically extended to the following workday.

REVIEW CONSIDERATIONS

Applications will be assigned for review to, and awards made by, the Fogarty International Center, utilizing the customary NIH peer review process. Scientific and technical merit are evaluated by a Fogarty International Center initial review group. Second level review is provided by the Fogarty International Center Advisory Board.

AWARD CRITERIA

Award decisions are made by the Director, FIC, and are based on the scientific merit of the applications, program policy considerations, and the availability of funds. Awards are announced as soon as possible following each Advisory Board meeting.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Mirilee Pearl
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

Direct inquiries regarding grants management and fiscal matters to:

Ms. Silvia Mandes
Grants Management Office
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
FAX: (301) 402-0779

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.934. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EFFECTS OF SIGNAL PROCESSING ON SPEECH UNDERSTANDING IN QUIET AND IN NOISE

NIH GUIDE, Volume 23, Number 3, January 21, 1994

PA NUMBER: PA-94-030

P.T. 34; K.W. 0715055, 0775005, 0740030

National Institute on Deafness and Other Communication Disorders

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) invites applications for support of research addressing the effects of signal processing on speech understanding in quiet and in noise. The goal of this Program Announcement (PA) is to stimulate basic research in a wide range of scientific disciplines to increase our understanding of normal and impaired auditory systems' responses to speech sounds that are processed through hearing aids, especially in the presence of background noise. This information will ultimately help to guide the development of improved hearing aids.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Effects of Signal Processing on Speech Understanding in Quiet and in Noise, is related to the priority area of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply for the First Independent Research Support and Transition (FIRST) (R29) award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support mechanisms appropriate for this announcement include the individual research project grant (R01) and the FIRST (R29) award.

RESEARCH OBJECTIVES

Background

Hearing aids continue to be the principal management of choice for most people with sensorineural hearing loss. Unfortunately, hearing aids often provide limited benefit, especially in noisy conditions. Progress in the miniaturization of circuits and transducers now allows a wide range of signal processing functions to be incorporated into very small devices. Many of these processing functions may improve the understanding of speech in noisy environments. However, the increased signal processing potential of hearing aids may soon surpass, or has already surpassed, the basic understanding of audition required to utilize the technology optimally. For example, the information-bearing acoustic parameters and units of speech are not yet fully understood. Nor is it known how the characteristics of hearing impairment (e.g., reduced or altered spectral and temporal processing abilities, increased linearity of the auditory system) affect the perception of various speech parameters. Even less well understood is how both normal and impaired auditory systems perform under the conditions imposed by the signal processing technologies of hearing aids (e.g., listening at high intensity levels, increased masking, temporal and spectral changes in signals).

Studies designed to investigate the problem of hearing in noise date back to the early development of hearing aids. Numerous studies have confirmed that, in contrast to individuals with normal hearing, hearing-impaired subjects perform poorly on speech intelligibility tasks in noisy conditions. The cause of that poor performance has yet to be defined adequately. Early studies have shown that both frequency and temporal resolution are poorer in listeners with sensorineural hearing loss than in listeners with normal hearing. These differences are attributed to such factors as abnormal spread of masking, broader peripheral filtering, and longer time constants for recovery from forward masking. However, some recent studies also support the possibility that the effects attributed to deficits in frequency selectivity and temporal processing in hearing-impaired listeners may in fact result from abnormal rates of growth of response to acoustic stimuli in the impaired ear. In this view, underlying properties of auditory filters and time constants remain unaltered in the impaired ear, and recruitment becomes the primary phenomenon in abnormal suprathreshold response. Additionally, some data suggest that the hearing-impaired subjects' poor performance can be explained largely on the basis of differences in audibility due to decreased hearing sensitivity, masking effects, and/or speech presentation level.

Few studies have examined the effects of signal processing by hearing aids on audition using either normal or hearing-impaired subjects. It is probable that the difficulties in speech understanding experienced by individuals with sensorineural hearing losses, which are often associated with auditory processing abnormalities in addition to a loss of sensitivity, may be exacerbated by the high intensities of sound processed through hearing aids. It is proving to be difficult to predict how a given signal processing strategy or circuit, with high presentation levels and many changes in temporal and spectral characteristics, will process continually changing speech signals. Furthermore, the interaction of the processed acoustic signal with the remaining capabilities of the impaired auditory system has never been systematically explored. A more thorough understanding of the effects of signal processing on audition is needed in order to guide the development of and to allow the proper utilization of improved hearing aids. Similarly there is need for a better understanding of the theoretical and practical issues of the physiologic, perceptual and communicative processes of hearing-impaired persons under conditions relevant to the use of hearing aids.

Research Goals and Scope

Studies are encouraged that are designed to assess the response of individuals with normal and impaired auditory systems to sounds that are processed through hearing aids, in the conditions normally encountered by hearing aid users. Noises and other experimental variables representative of real listening environments should be used when possible. The use of experimental designs that minimize the confounding effects of threshold and presentation levels on estimates of subject performance are desirable.

Areas of research that would be responsive to this PA include, but are not limited to:

- o studies of the influences of processing speech through hearing aids (e.g., high presentation levels, changes in temporal and spectral characteristics) on the understanding of speech sounds in quiet and in noise for normal and impaired auditory systems;
- o studies in quiet and in noise designed to assess the interaction between the processed acoustic signal and the impaired auditory system having such features as reduced frequency selectivity, limited dynamic range, and abnormal growth of loudness;
- o studies of methods of predicting speech recognition with hearing aids in quiet and in noise for normal and impaired auditory systems;
- o studies designed to examine the relationship between optimal speech spectrum audibility and loudness tolerance under conditions relevant to hearing aid use in normal and impaired auditory systems in quiet and in noise;
- o studies of the effects of reverberation on speech recognition under conditions relevant to hearing aid use by normal and impaired auditory systems in quiet and in noise;
- o studies of changes in speech recognition performance as a function of intensity level with consideration of the factors involved in audibility in quiet and in noise in normal and impaired auditory systems;
- o studies of psychoacoustic performance measures (e.g., discrimination of spectral contrast, frequency resolution, sensitivity to subtle temporal factors within complex sounds) under conditions relevant to hearing aid use in normal and impaired auditory systems in quiet and in noise.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific questions(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7250. The title and number of the announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of references letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered as funding decisions are made:

- o quality of the proposed project as determined by peer review,
- o availability of funds, and
- o program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be addressed to:

Amy M. Donahue, Ph.D. or Lynn E. Huerta, Ph.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-C
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-3458
FAX: (301) 402-6251

Inquiries regarding fiscal matters may be addressed to:

Sharon Hunt
Division of Extramural Activities
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-B
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-0909
FAX: (301) 402-1758

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

**EXTRAMURAL RESEARCH FACILITIES CONSTRUCTION PROJECTS**

NIH GUIDE, Volume 23, Number 3, January 21, 1994

RFA: RR-94-003

P.T. 02; K.W. 0710030

National Center for Research Resources

Letter of Intent Receipt Date: February 18, 1994

Application Receipt Date: April 8, 1994

The following modification is made to Request for Applications (RFA) RR-94-003, which appeared in the NIH Guide for Grants and Contracts, Vol. 23, No. 1, January 7, 1994.

Under the section RESEARCH OBJECTIVES, the sentence beginning, "Applications proposing to broaden the scope..." should be substituted with the following language:

"Applications are particularly encouraged from institutions of emerging excellence as defined in the PHS Act, Section 739 as amended by PL 102-408, as are applications that propose to (a) broaden the scope of research and research training programs of the institutions by promoting interdisciplinary research; research on emerging technologies (including those involving novel analytical techniques or computation methods); or other novel research mechanisms or programs; (b) broaden the scope of research and research training programs of qualified institutions by promoting genomic research with an emphasis on interdisciplinary research, including research related to pediatric investigations."

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

RICHARD W MURRY

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929 WILD FOREST DRIVE
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Vol. 23, No. 4
January 28, 1994

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NOTICES

IMMUNE RESPONSES TO LYME DISEASE INFECTION AND VACCINATION

NIH GUIDE, Volume 23, Number 4, January 28, 1994

RFA: AI-94-008

P.T.

National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: February 7, 1994

Application Receipt Date: March 18, 1994

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) will join with the National Institute of Allergy and Infectious Diseases (NIAID) to co-sponsor the Request for Application (RFA) AI-94-008 entitled "Immune Responses to Lyme Disease Infection and Vaccination," published in the NIH Guide for Grants and Contracts Vol. 23, No. 1, January 7, 1994. The NIAMS has a continuing interest in the support of research on Lyme disease, particularly its chronic and arthritic manifestations.

Applications received in response to this RFA that focus on issues relating to chronic Lyme disease, particularly arthritis, will be considered for funding by both the NIAID and NIAMS.

INQUIRIES

Interested investigators are encouraged to contact Program Staff to discuss potential applications and to obtain the full text of the amended RFA. Inquiries may be addressed to:

Dr. Susana A. Serrate-Sztejn
Rheumatic Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 594-5593
FAX: (301) 480-7881

SYNTHESIS OF CONGENERS AND PRODRUGS

NIH GUIDE, Volume 23, Number 4, January 28, 1994

RFP AVAILABLE: NCI-CM-47012-20

P.T.

National Cancer Institute

The Drug Synthesis and Chemistry Branch (DS&CB) of the Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) is seeking contractors with expertise in chemical synthesis and drug design to synthesize a variety of compounds for evaluation as potential anti-AIDS or anti-cancer agents. The assigned objectives of this project are to design and synthesize the following: (a) congeners of lead compounds having confirmed activity to enhance activity or potency; (b) prodrugs with structural modifications that may provide altered pharmacokinetics, altered drug transport, improved bio-availability through increased water solubility, or increased chemical stability; (c) other altered structures that possess elements of both congeners and prodrugs; and (d) compounds related to natural products, e.g., alkaloids, heterocycles, nucleosides, and peptides.

Each contractor should have available a fully operational facility, including all necessary equipment and instrumentation for all aspects of the contract. The nature of this project requires that the following restriction be applied: "The NCI signs legally binding agreements with certain suppliers (often pharmaceutical or chemical companies) that state that all information on compounds submitted by the supplier will be held confidential. The successful offeror will be expected to synthetically modify such commercially confidential (discreet) materials. Thus, pharmaceutical or chemical companies could obtain valuable data on new lead compounds. Therefore, in order to honor the confidentiality agreement with the original supplier, the NCI believes that the compounds cannot be sent to potential competitors of the supplier, and thus pharmaceutical and chemical companies must be excluded from the competition." For purposes of this restriction, a pharmaceutical or chemical company is defined as an organization that sells drugs and chemicals to the general public for profit. The Standard Industrial Classification (SIC) number is 8731. This is a recompetition of contracts currently held by the Georgia Tech Research Corporation (Georgia Institute of Technology), Purdue Research Foundation, and the University of Tennessee. It is anticipated that two cost-reimbursement contracts will be awarded for a period of two years beginning on or about September 30, 1994.

INQUIRIES

Request for Proposals (RFP) No. NCI-CM-47012-20 will be issued on or about January 31, 1994 and proposals will be due approximately 30 days thereafter. Copies of the RFP may be obtained by sending a written request to:

Charles Lerner
Research Contracts Branch, TCS
National Cancer Institute
Executive Plaza South, Room 603
Bethesda, MD 20892
Telephone: (301) 496-8603

PHYSICAL ACTIVITY INTERVENTION IN HEALTH-CARE SETTINGS FOR HIGH-RISK SEDENTARY ADULTS - COORDINATING CENTER

NIH GUIDE, Volume 23, Number 4, January 28, 1994

RFP AVAILABLE: NHLBI-HC-94-07

P.T.

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) is soliciting proposals for a Coordinating Center to participate in a multicenter clinical trial designed to develop and evaluate the effectiveness of various intervention approaches delivered in health-care settings in increasing and maintaining physical activity and cardiorespiratory fitness among sedentary men and women at elevated risk of coronary heart disease (CHD) by blood pressure (BP) or lipoprotein criteria. The study will also examine the cost-effectiveness of the various intervention approaches as well as the magnitude of effects on BP, lipoproteins, and weight and the long-term maintenance of those effects. In addition to one Coordinating Center to be awarded under RFP No. NHLBI-HC-94-07, an estimated total of three clinical center contracts will be awarded under a separate RFP.

The Coordinating Center will have responsibility for the overall coordination, monitoring, and central management of all activities, including data entry and management, quality control, data analysis, and collaborative development of the study protocol, manual of operations, interventions, and data collection procedures. The Coordinating Center will also be charged with the responsibility of competitively selecting a Central Blood Laboratory to perform as a subcontract to the Coordinating Center after contract award. A planned total of 810 adult subjects will be randomized into three intervention groups and one comparison group. This will be a five year study with a projected award date of September 30, 1994. The primary study outcomes will be cardiorespiratory fitness (i.e., maximum oxygen uptake) and physical activity (frequency, intensity, duration, and estimated caloric expenditure). Because of the need for scientifically comparable data in a defined population and relevance to the U.S. health care system, offerors other than U.S. institutions will not be considered. This procurement will be a new award and is open to all offerors who meet the determination of responsibility as defined by FAR 9.104.

INQUIRIES

Request for Proposals (RFP) No. NHLBI-HC-94-07 is now available. Letters of Intent will be due two weeks after the release date of the RFP. Proposals will be due on March 21, 1994. All requests for this RFP must be submitted in writing, verbal requests will not be accepted. Written requests must reference RFP No, NHLBI-HC-94-07, include three self-addressed mailing labels, and be addressed to:

John C. Taylor
Contracting Office
National Heart, Lung, and Blood Institute
7550 Wisconsin Avenue
Federal Building, Room 200
Bethesda, MD 20892
Telephone: (301) 496-9655

SURFACE MODIFICATION FOR BIOCOMPATIBILITY

NIH GUIDE, Volume 23, Number 4, January 28, 1994

RFP AVAILABLE: NIH-NINDS-94-04

P.T.

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, is seeking a contract to create surfaces on implantable silicon microstructures for the purpose of controlling the interaction of neurons, glia, and related cells and their protein products with the microstructure. Biomaterials that penetrate into the central nervous system as the microscopic electrode shafts of the neural prostheses interact with neural and other tissues on a cellular and molecular level. In order to achieve tight coupling between these implanted microelectrodes and the target neural substrate, this interaction must be understood and controlled. This contract supported research will study these interactions with a long-term goal of rationally designing microelectrode surfaces to promote specific tissue interactions. The efficiency of these microelectrodes depends on the micro environment around stimulating sites. The surface of the microelectrodes and the proteins that adsorb to this surface have a major impact on the way in which different cell populations react to the implant. Neural growth cones are sent out from many neurons around a microelectrode following implantation. With appropriate surfaces it may be possible to get selected neurons to send processes directly to the microelectrodes. This study will investigate cellular and molecular responses to specific surface modifications of silicon microelectrodes. Personnel with established expertise in cell biology and surface science are needed. It is anticipated that one award will be made for a period of three years. Award is anticipated for September 1994.

INQUIRIES

This is not a Request for Proposals (RFP). RFP NIH-NINDS-94-04 will be issued on or about February 1, 1994 with proposals due on April 4, 1994. To receive a copy of the RFP, submit a written request along with two self-addressed mailing labels to:

Laurie Leonard
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
ATTN: RFP NIH-NINDS-94-04

All responsible sources shall be considered by the agency.

RESEARCH ON ORAL WOUND HEALING AND TISSUE REGENERATION

NIH GUIDE, Volume 23, Number 4, January 28, 1994

PA NUMBER: PA-94-031

P.T.

National Institute of Dental Research

PURPOSE

The National Institute of Dental Research (NIDR) invites investigator-initiated grant applications to conduct multidisciplinary basic and clinical research on wound healing and tissue regeneration associated with the orofacial region. Applications that address the healing, regeneration and repair of oral tissues following periodontal diseases, trauma, and surgical treatment of birth defects such as cleft lip and palate and cancer are sought through this Program Announcement (PA).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Oral Wound Healing and Tissue Regeneration, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit and for-profit, public and private organizations, such as dental or medical schools, universities and research institutions. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms available for the support of research in response to this PA include the traditional research project grant (R01), FIRST (R29) Award, small grant (R03), and Interactive Research Project Grants. Responsibility for the planning, direction, and execution of the projects will be solely that of the applicants.

RESEARCH OBJECTIVES

Background

Wound healing is a complex process in which a variety of cellular and matrix components act in concert to reestablish the integrity of injured tissue. The complexity of this process may be simplified into four broad categories of the healing response that coincide with the temporal sequence of normal healing: hemostasis; inflammation; cell proliferation (repair); and tissue remodelling. The problems of repair and regeneration of orally related tissues, however, have certain unique features. For example, materials used in osseous reconstruction of the jaw must withstand extreme physical stresses. Moreover, the presence of teeth in the wound area can expose the underlying tissues of the oral environment and thus complicate the healing process. In addition, microorganisms and the host response to microorganisms in the oral cavity can prevent or significantly prolong healing of damaged tissues.

The purpose of this PA is to further both basic and clinical research relevant to wound healing and tissue regeneration following periodontal diseases as well as various types of orofacial trauma, such as surgical treatment of cleft lip and palate, ablation and reconstructive treatment for cancer of the orofacial area, and regeneration of functional salivary glands following chemotherapy and radiation. A brief description of the relevant portions of the three major NIDR program areas covered by this PA follows.

Craniofacial Injuries and Disorders

The craniofacial region is especially susceptible to injuries and wounds resulting from motor vehicle crashes, motorcycle and bicycle related accidents, injuries associated with sports and recreation, and interpersonal violence. Additional sources of trauma include surgical correction of congenital craniofacial deformities. Successful management of injuries and wounds of the craniofacial structures presents unique challenges. The diversity of tissues and structures in close proximity to each other and the variety of functions in which they participate, including speech, hearing, breathing, mastication and swallowing, compound the problem of treating orofacial trauma. Wound healing following reconstructive surgery must often accommodate tissue deficits, such as large bony defects, thus compounding problems of the wound healing process.

Oral Cancer

The management of cancer of the orofacial complex similarly presents a unique challenge to the health care profession. Cancer therapy may involve surgery, chemotherapy, radiation therapy, or any combination of the three. The variety of tissues that comprise the orofacial complex (e.g., glandular secretory tissues, connective and mucosal tissues) respond in select fashion to ablative and reconstructive treatment of tumors of the head and neck. Restoration of optimal function and normal appearance is a principal goal of the care and management of tumors of the head and neck. Because of the recurring nature of many types of cancers, therapy frequently must be repeated, often complicating the healing process. A serious side effect of therapy, especially that involving radiation or chemotherapy, is damage to the salivary glands and the immune system, which can in turn lead to a general impairment of healing, repair, and

regeneration of the oral tissues.

Periodontal Diseases

Periodontal diseases comprise a group of related microbial- induced chronic inflammatory disorders that destroy the tissues supporting the teeth. These diseases can result in loss of substantial bone and soft tissue around the affected teeth, which challenges the clinician's efforts to restore full structure and supporting function to the periodontium. Periodontal healing is complicated by microbial recolonization of the subgingival sulcus, systemic diseases (e.g., diabetes), conditions in which there is direct bone contact with the root cementum (ankylosis), and the downward migration of epithelial cells, which prevents the reattachment of the fibrous periodontal ligaments to the cementum and alveolar bone. Major goals of periodontal therapy are, therefore, to inhibit microbial recolonization, prevent epithelial interference with proper integration of the soft and hard tissues, accelerate complete reformation of the lost alveolar bone without ankylosis or root resorption, reestablish a complete periodontal ligament network, and restore healthy gingival soft tissues. Major gaps exist in our understanding of the mechanisms by which healing of the periodontium can be accelerated and or enhanced by the clinician. Guided tissue regeneration of the periodontium, for example, while no longer considered experimental, remains an evolving technology requiring further research.

Scope

A selection of research topics appropriate for this PA is identified below. This list is illustrative and not exclusive, restrictive or in priority order. Investigators are encouraged to submit scientifically meritorious applications in any area of research responsive to the overall research objectives of this PA. Projects should be founded on a strong hypothesis as evidenced by preliminary data. Prior experience of the investigative team is an important element in demonstrating the likely success of the research proposed.

o Molecular and Cellular Basis of Healthy Tissues

Investigations that address the molecular and cellular characteristics of healthy oral tissues and their mechanisms for regeneration are central to understanding the goals of successful wound healing therapy. These studies include the role of cell adhesion molecules, isolation and characterization of tissue progenitor cells, normal gene expression in oral tissues, and molecular basis of homeostatic tissue cell replacement. In addition, studies of the influence of anatomical features, such as tooth root furcations, on proper healing of the oral tissues are needed. Investigations that identify cell lineages (e.g., cementoblasts) associated with periodontal wound healing are also appropriate. Also, studies that would advance an understanding of the molecular and cellular basis of periodontal guided tissue regeneration, as well as improve the methodology involved, are strongly encouraged.

o Cytokines, Growth Factors, and Biological Response Modifiers

Cytokines and polypeptide growth factors, including angiogenic growth factors and bone morphogenetic proteins, have been shown to regulate many of the processes involved in wound healing both in vitro and in animal models. The precise role of these factors in wound healing in the orofacial area requires further delineation. As some growth factors affect specific stages of healing and cell types in a temporal manner, it may be necessary to combine certain growth factors for complex wounds and to determine the optimal time for delivery of the factors. Furthermore, biological response modifiers that can control the activities of cytokines and growth factors need to be identified and characterized. The use of genetic therapies to deliver the genes for these proteins to the injured or defective sites represents an exciting contemporary approach for enhancing orofacial wound healing.

o Biomaterials

Development of new bone-derived, metallic, and synthetic materials for osseous reconstruction is central to the advancement of repair and regeneration of craniofacial and periodontal tissues. Moreover, the use of bone-inductive techniques with appropriate biodegradable and non-biodegradable scaffolding materials appears to offer new modalities for the treatment of congenital or acquired bone defects. Also, studies are needed to develop methods to evaluate the long-term performance of biomaterials, such as hydroxyapatite, ceramic, and coral implants, which are used in the repair of orofacial bone defects. Recent advances in the use of modified collagen matrices for the reconstruction of oral soft tissue, including the mucosal surfaces of the mouth, promise improved materials for soft tissue regeneration. Resorbable barrier materials, such as those used in guided tissue regeneration, are needed to prevent migration of tissues that interfere with structural and functional repair of the oral tissues.

o Nutrition

Wound healing is affected by a wide variety of metabolic and nutritional factors. Their effects on reparative and defense mechanisms are complex, additive and often synergistic. Studies are needed to determine the effects of nutritional factors on the regenerative process of oral tissues. Since metabolic and nutritional deficiencies can increase oral tissue susceptibility to injury and prolong the healing process, studies that will identify and establish effective treatment plans to prevent or correct the deficiencies are needed.

o Aging, Systemic and Behavioral Conditions

Studies are needed to clarify the mechanisms through which aging, systemic diseases (e.g., diabetes, Paget's disease), and behavioral practices (e.g., alcohol consumption, smoking) influence oral wound healing. Studies are also needed to develop improved means for promoting oral wound healing under such adverse conditions.

o Radiation and Chemotherapy

Radiation and chemotherapy have profound effects on the immune system, cell proliferation and tissue growth. These treatments appear to influence the healing process. Studies are therefore needed to define the effects of radiation and chemotherapy on, for example, production of cytokines and growth factors by oral tissues, the stability and integration of reconstructive biomaterials, and the molecular mechanisms involved in oral tissue damage.

o Models of Oral Wounds

The investigation of oral wound healing has been hampered by a lack of in vitro and suitable animal models. Furthermore, sensitive methods to quantify the histological, immunological, and biochemical events in the wound are needed. Models are needed in which it would be possible to study the effect of, for example, chronic inflammation, cytokines and growth factors, biomaterials, free radicals, aging, diabetes, or tobacco smoke on orofacial wound healing. The use of transgenic and gene knockout animals might provide important models for studying oral wound healing.

o Technology Transfer and Clinical Application of Basic Science

This PA encourages collaborative research efforts among clinicians, materials scientists, and basic scientists to transfer the knowledge gained in the laboratory to the clinical arena. Cooperative efforts between universities and for-profit as well as not-for-profit private organizations are encouraged in order to develop commercial applications that promote oral wound healing.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample site appropriate for the scientific objectives of the study. This information should be included in form PHS 398 (rev. 9/91) in items 1-4 of the Research Plan and summarized in item 5, Human Subjects. Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all such projects to include representation of the full array of United States racial, ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed or the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to the NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on grant application form PHS-398 (rev. 9/91), which may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248, and from the institution's office of sponsored research. To identify the application as a response to this PA, check "YES" on item 2a on the face page of the application and enter PA-94-031, "Wound Healing and Tissue Regeneration."

Applications will be accepted at the standard application deadlines indicated in the application kits.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

A signed, typewritten original of the application, and five signed photocopies, in one package must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**



Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by initial review groups of the Division of Research Grants, NIH, or by the review group of the relevant Institute in accordance with the standard NIH peer review procedures. Following scientific-technical review, applications will receive a second level review by the appropriate national advisory council or board.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that institute, center or division. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Mohandas Bhat, M.D.S., Dr.P.H.
Director, Craniofacial Development and Disorders Program
Telephone: (301) 594-7648

Matthew A. Kinnard, Ph.D.
Director, Oral Soft Tissue Diseases and AIDS Program
Telephone: (301) 594-7641

Dennis F. Mangan, Ph.D.
Director, Periodontal Diseases Program
Telephone: (301) 594-7641

Extramural Program
National Institute of Dental Research
Westwood Building Room 509
Bethesda, MD 20892

Direct inquiries regarding fiscal matters to:

Ms. Theresa Ringler
Grants Management Office
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, (42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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Bethesda, MD 20816***

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Vol. 23, No. 5
February 4, 1994

RICHARD W. HURRY

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S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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NOTICES

EQUIPMENT FOR EXISTING AND DEVELOPING NCI CANCER CENTERS

NIH GUIDE, Volume 23, Number 5, February 4, 1994

P.T. 34; K.W. 0735000

National Cancer Institute

The National Cancer Institute (NCI) is issuing a "letter" Request for Applications (RFA) to institutions that have been awarded Cancer Center Support Grants (CCSGs or P30s) or Cancer Center Planning Grants (P20s) to provide important equipment and instrumentation needs in cancer research. The awards are in the form of one-time supplements with no outyear commitments. Equipment requested should be for items not generally considered to be "portable" and/or generally not available through the traditional research grant mechanisms (e.g., R01s, P01s). These types of equipment normally require dedicated space; serve as a resource for several peer-reviewed, funded research projects; and are centrally managed by the cancer center. Requests can be for a single piece of equipment, an upgrade to a piece of equipment or

an existing facility, or several pieces of equipment that are components of an integrated setup. Up to \$2 million in total costs will be committed to fund applications that are submitted in response to the "letter" RFA. Institutions with P30s will be limited to one request and are required to provide matching funds of 50 percent of the costs of the equipment. Institutions with P20s will be limited to two requests and are encouraged to provide matching funds of 50 percent of the costs of the equipment. Requests broadly related to breast cancer, prostate cancer, or other areas designated as areas of "high priority" research would be especially welcome; however, applications need not be limited to these cancers.

INQUIRIES

The receipt date for applications is March 1, 1994 and awards are anticipated before September 30, 1994. A copy of the complete "letter" RFA may be requested from:

Ms. Anna Levy
Division of Cancer Biology, Diagnosis and Centers
National Cancer Institute
Executive Plaza North, Room 502
Bethesda, MD 20892
Telephone: (301) 496-8537

NOTICES OF AVAILABILITY (RFPs AND RFAs)

RESEARCH REGISTRIES FOR RARE DISEASES OR GROUPS OF DISEASES OR CONDITIONS OF INTEREST TO THE NATIONAL INSTITUTES OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

NIH GUIDE, Volume 23, Number 5, February 4, 1994

BAA AVAILABLE: NIH-NIAMS-94-2

P.T. 34; K.W. 0780030, 0715010

National Institute of Arthritis and Musculoskeletal and Skin Diseases

This is a Broad Agency Announcement (BAA) that describes in general terms a research topic and outlines proposal preparation requirements. The work requirements are developed and defined by the offeror and not the Government. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking to award two to three five-year cost-reimbursement contracts for the establishment of Registries of patients and/or families with diseases or groups of related diseases or conditions that are related to ongoing basic and/or clinical research. The Registries will be aimed at searching for basic defects, improving methods of diagnosis, and/or developing effective methods in treatment and prevention.

INQUIRIES

The BAA will be issued on or about February 11, 1994 with proposals due on April 12, 1994. All responsible sources will be considered by the agency. No collect calls will be accepted. To receive a copy of the BAA, reference BAA NIH-NIAMS-94-2, supply this office with two self-addressed mailing labels, and submit a written request to:

Lynn Wheeler
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 420
Bethesda, MD 20892
Telephone: (301) 594-7854

NIH GUIDE, Volume 23, Number 5, February 4, 1994

RFA AVAILABLE: HG-94-001

P.T.

National Center for Human Genome Research
National Cancer Institute
National Institute of Mental Health
National Institute of Nursing Research

Letter of Intent Receipt Date: March 1, 1994

Application Receipt Date: April 22, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

This RFA will solicit projects designed to examine the psychosocial and clinical impact of using gene-based diagnostic tests in families with heritable forms of breast, ovarian, and colon cancer to identify those individuals who have an increased risk of developing cancer and those who do not; and to gather information needed to establish clinical protocols for the optimum use of these risk assessment technologies in the future.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Studies of Genetic Testing and Counseling for Heritable Breast, Ovarian, and Colon Cancer Risks, is related to the priority areas of health promotion and cancer prevention. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) and small research grant mechanisms (R03). Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

FUNDS AVAILABLE

It is anticipated that \$2,400,000 (total cost) per year for up to three years will be available beginning in fiscal year 1994 for approximately eight to ten studies. This level of support is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the participating institutes, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The goal of these studies is to identify clinical practices that best increase individual and provider understanding of genetic testing for cancer risks; the meaning and implications of test results; and strategies to promote health, prevent the development of cancer, and reduce the risk for test-related psychological harm, stigmatization and discrimination in individuals tested and their families. Multidisciplinary research teams are encouraged to respond to this RFA. Research questions that may be appropriately addressed in applications responding to this RFA could include, but are not limited to: (1) identifying individuals who are most likely to benefit from genetic testing for heritable cancer risks; (2) determining optimum ways to educate individuals considering having genetic tests for cancer risk assessment, including public education and education through support groups; (3) establishing mechanisms to assess individual readiness for genetic testing for cancer risks (including minors and other individuals with diminished autonomy, in whom testing may be recommended) and determining factors that influence the decision to be tested; (4) defining issues that should be addressed in the informed consent process for individuals in families considering genetic testing and counseling for cancer risks, including the potential for the use of persuasion within families, changes in family dynamics, and stigmatization or discrimination; (5) examining diverse models (including a variety of settings and providers) of delivery for providing genetic testing and counseling for cancer risks; (6) identifying and evaluating strategies for providing post-test counseling and follow up for individuals who have had genetic tests for cancer risks (for both those individuals who were found to have an increased risk and those who were not); (7) determining what the psychosocial impact is on individuals who learn through genetic testing that their risk to develop cancer is either substantially increased above or no greater than that of the general population (especially as it pertains to family relationships, subsequent health behavior, reproductive intentions, and quality of life); (8) defining the impact of genetic diagnosis for cancer risk on subsequent interactions with health professionals and third party payers; (9) examining the behavior and actions of non-test-takers, including women, men and non-tested minors; (10) ascertaining attitudes, levels of understanding and interest in genetic testing to determine cancer risk in provider populations by whom testing might be offered in the future, distinguishing discipline, training, gender and ethnocultural differences;

(11) ascertaining attitudes, levels of understanding and interest in genetic testing for cancer risks in individuals and families with diverse ethnocultural backgrounds to whom genetic testing for cancer risks may be offered in the future; and (12) examining the economic impact and technical accuracy of various genetic testing strategies for determining cancer risks in families and other populations, including analysis of associated health care costs placed in the context of health outcomes related to early detection and interventions to reduce risks.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIH staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Elizabeth J. Thomson at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301)594-7248. Additional instructions for preparation of applications are provided in the RFA. Applications must be received by April 22, 1994. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NCHGR program staff for completeness and responsiveness to RFA. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIH staff will contact the applicant to determine whether to return the application to the applicant or submit it to the Division of Research Grants (DRG) for review in competition with unsolicited applications at the next review cycle.

Applications may be triaged by an NIH peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Those applications that are complete and responsive will be evaluated by an appropriately constituted initial review group in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by NCHGR. The second level of review will be provided by the appropriate National Advisory Councils.

AWARD CRITERIA

The number of awards and the specific amount to be awarded will depend on the merit and scope of the applications received and on the availability of funds. The anticipated date of award approximately September 30, 1994.

INQUIRIES

It is essential that prospective applicants obtain a copy of the complete RFA before preparing an application. Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. To obtain a copy of the RFA or to inquire about programmatic issues, contact:

Elizabeth J. Thomson, M.S., R.N.
Ethical, Legal, and Social Implications Branch
National Center for Human Genome Research
Building 38A, Room 617
Bethesda, MD 20892
Telephone: (301) 402-4997
FAX: (301) 480-2770

Inquiries regarding fiscal matters may be directed to

Jean M. Cahill
Grants and Contracts Management Section
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172, Human Genome Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

APPLIED RESEARCH RELEVANT TO AN ELECTRONIC MEDICAL RECORD

NIH GUIDE, Volume 23, Number 5, February 4, 1994

RFA AVAILABLE: LM-94-002

P.T. 34; K.W. 0710078, 0730045

National Library of Medicine

Letter of Intent Receipt Date: March 28, 1994

Application Receipt Date: April 27, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Library of Medicine (NLM) and the Agency for Health Care Policy and Research (AHCPR) invite applications for cooperative agreements for applied research and development projects relevant to the development of an electronic medical record system (EMRS).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000", a PHS-led national activity for setting priority areas. This RFA, Applied Research Relevant to an Electronic Medical Record, is related to the priority area of surveillance and data systems. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000: (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government. Applications from minority individuals and women are encouraged. Only domestic organizations are eligible to apply. Domestic applications may not have international components. The NLM, but not the AHCPR, is also authorized to award grants to domestic for-profit organizations.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U01), an assistance mechanism (rather than an acquisition mechanism) in which substantial PHS scientific and/or programmatic involvement with the awardee is anticipated during the performance of the activity. Details of the responsibilities, relationships, and governance of the study to be funded under this cooperative agreement are discussed in the RFA. The total project period for applications submitted in response to this RFA may not exceed three years. The anticipated award date is September 1994. Because the nature and scope of the research proposed in response to this RFA may vary, the award size will vary also. However, it is anticipated that most of the awards made will have a total annual cost between \$250,000 and \$500,000.

FUNDS AVAILABLE

Funds available for the first year of support for the RFA are approximately \$1,300,000; however, expenditure of this commitment amount is conditional upon the receipt of applications of high scientific merit. Number of awards to be made are estimated to be between three and six. Although the PHS budget is expected to permit support of these projects, funding of applications pursuant to this RFA are contingent upon the availability of funds at the appropriate time.

RESEARCH OBJECTIVES

A digital record system can facilitate greatly the efforts of health care providers and health services research workers, and can furnish vital information to planners, evaluators, regulators, and payers. This RFA is designed to foster development of working systems suitable for both inpatient and outpatient care, and capable of providing data useful in health services research, including technology assessment and outcomes research.

Objectives and Scope

Applications must be relevant to an Electronic Medical Record System, broadly defined, and should clearly recognize the interest of PHS in testable solutions to one or more of the myriad problems associated with development and implementation of a useful EMRS. Great importance is placed on widely-useful models. Applicants should understand that this RFA emphasizes projects that can be expected to have practical application in the near term; applications are expected to include a plan for demonstrating the practicality and utility of the proposed work.

The NLM has a particular interest in applications that address clinical vocabulary issues relevant to an EMRS. The AHCPR has particular interest in applications that address improvements in delivery of health services through the use of an EMRS.

SPECIAL REQUIREMENTS

The Principal Investigator will be expected to attend and participate in two one-day progress report and planning meetings per year as a member of the steering committee. (See below). Applicants are advised to assume such meetings will be held in Bethesda, MD. Applications should discuss the rationale for the choice of hardware, software, protocols, and standards. Applicants should discuss their plans for testing the project work in a model or working system.

Terms and Conditions of Award

Awardee Rights and Responsibilities

The Principal Investigator will have primary responsibility for the development of the specific research approach. The Principal Investigator will retain custody of and primary rights to data developed under this RFA, subject to government rights of access, consistent with current HHS, PHS, AHCPR, and NIH policies.

NLM and AHCPR Responsibilities

To implement the cooperative agreements, NLM's Associate Director of Extramural Programs will serve as the project's scientific coordinator. A steering committee, composed of all PIs funded under this RFA, the Scientific Coordinator, and one other Federal staff member will function as the governing board for the work done under the RFA. Each steering committee member will have one vote. One of the PIs will be selected by the committee members to serve as chairperson.

PHS reserves the right to terminate or curtail an individual award.

Collaborative Responsibilities

Awardees may be asked to collaborate with others. Awardees are expected to cooperate reasonably with the decisions of the steering committee.

Arbitration

Any disagreement that may arise on scientific/programmatic matters within the scope of the award between award recipients and PHS may be brought to arbitration.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 28, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the principal investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows PHS staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Mr. Peter Clepper
Division of Extramural Programs
National Library of Medicine
Building 38A, Room 5S-518
Bethesda, MD 20894
Telephone: (301) 496-4221
FAX: (301) 402-0421
E-mail: clepper@nlim.nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these cooperative agreements. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone: 301-594-7248; and from the Division of Extramural Programs, National Library of Medicine, Building 38A, Room 5S-518, Bethesda, MD 20894, telephone 301-496-4221.

Applicants are urged to note the special features described in the SPECIAL REQUIREMENTS and Terms and Conditions of Award sections of the RFA.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form, and the 'YES' box must be marked.

Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must be sent to Mr. Peter Clepper at the address listed under LETTER OF INTENT.

Applications must be received by April 27, 1993. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed, but will accept substantial revisions of applications already reviewed with the understanding that such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

All applications will be judged on the basis of the scientific and technical merit of the proposed research, and the degree to which they address the RESEARCH OBJECTIVES of the RFA. Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by NLM and AHCPR. Incomplete applications will be returned to the applicant without further consideration. Complete applications will be evaluated in accordance with the criteria stated below by an initial review group to be convened by NLM. Second-level review will be conducted by the Board of Regents of NLM and the National Advisory Council of AHCPR in accordance with applicable policies.

Applications may be subjected to triage if the number of applications is large compared to the number of awards to be made. If so, the NLM and the AHCPR will withdraw from further competition those applications judged to be non-competitive for an award and notify the applicant Principal Investigator and institutional official. Applications judged to be competitive will undergo further review.

The factors to be used in judging each application are:

- o Responsiveness in general to the objectives of the RFA
- o potential for furthering progress toward the goal of a national EMRS
- o compliance with the requirements noted in the SPECIAL REQUIREMENTS and Terms and Conditions sections of this RFA
- o Scientific and technical merit and significance
- o appropriateness of the approach and methodology
- o qualifications and experience of the PI and others involved in the project
- o availability of necessary resources
- o plans for demonstrating the utility of the project

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Milton Corn, M.D.
Division of Extramural Programs
National Library of Medicine
Building 38A, Room 5N505
Bethesda, MD 20894
Telephone: (301) 496-4621
FAX: (301) 402-0421
E-mail: corn@lhc.nlm.nih.gov

James McAllister, M.P.H.
Center for General Health Service Extramural Research
Agency for Health Care Policy and Research
2101 E. Jefferson Street, Suite 501
Rockville, MD 20852
Telephone: (301) 594-1439
FAX: (301) 594-2155
E-mail: jmcallis@po3.ahcpr.gov

Direct inquiries regarding fiscal matters to:

Mrs. Ruth Bortz
Division of Extramural Programs
National Library of Medicine
Building 38A, Room 5N507
Bethesda, MD 20892
Telephone: (301) 496-4243
FAX: (301) 402-0421
E-mail: bortz@lhc.nlm.nih.gov

Mr. Ralph Sloat
Grants Management Branch
Agency for Health Care Policy and Research
2101 E. Jefferson Street
Rockville, MD 20852
Telephone: (301) 594-1447
FAX: (301) 594-3210
E-mail: rsloat@po7.ahcpr.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.879, 93.180, and 93.226. Awards are made under authorization of the PHS Act, Title III, Part A, Section 301, Title IV, Part D, Subpart 2, Sections 472-476, as amended, Public Law 100-607 and Title IX, as amended (Public Laws 101-239 and 102-410) and administered under PHS grants policies and Federal Regulations 42 CFR 67, Subpart A and 45 CFR Part 74, (45 CFR Part 92 for State and local Governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DIAGNOSTIC METHODS TO ASSESS NEUROLOGIC INTEGRITY IN FETUS/NEONATE

NIH GUIDE, Volume 23, Number 5, February 4, 1994

RFA AVAILABLE: HD-94-011

P.T. 34; K.W. 0710085, 0745020, 0705035, 0775013

National Institute of Child Health and Human Development
National Institute of Neurological Disorders and Stroke

Application Receipt Date: April 29, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The objective of the RFA is to stimulate research on the development of effective technologies to assess the integrity and function of the developing brain in the human fetus and newborns. The long term goal of this research is the identification of newborns with brain dysfunction due to early, repetitive or chronic intrauterine central nervous system (CNS) influences/insults which may result in Sudden Infant Death Syndrome (SIDS) and developmental disabilities including cerebral palsy. Postnatally acquired and acute perinatal deficits are not within the scope of this RFA. The National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological Disorders and Stroke (NINDS) invite applications for studies in animals and/or humans that: (1) elucidate the physiological parameters that would serve as reliable markers of central nervous system integrity/pathology; and (2) explore the development of technologies/clinical tools that might identify infants who have or are at risk for abnormal neurologic development or sudden death.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Diagnostic Methods to Assess Neurologic Integrity in Fetus/Neonate, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) (R29) award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) and the FIRST Award (R29). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for R01 applications submitted in response to the present RFA may not exceed four years. R29 awards must be for five years. The earliest anticipated award date is September 30, 1994.

Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

The estimated direct costs available for the first year of support for the entire program is \$800,000 from the NICHD and \$600,000 from the NINDS. The anticipated number of new awards supported is four by the NICHD and three by the NINDS.

RESEARCH OBJECTIVES

The types of research approaches being sought by this RFA include but are not restricted to:

1. Studies in animals that model early, and/or recurrent, and/or chronic CNS influences/insults in utero and include assessments of central nervous system integrity in the fetus and neonate. Animal models must demonstrate relevance to the human fetus and neonate. The models should link severity of outcome with the nature of the insult (e.g., type, timing, duration, location). Examples of insults of interest include but are not limited to: hypoxia, hypoglycemia, hypovolemia, infectious agents, exposure to substances of abuse.
2. Studies in human fetal and neonatal subpopulations suspected of being exposed to recurrent and/or chronic insults in utero that assess central nervous system integrity and link assessment with outcome.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the program staff listed under INQUIRIES.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Susan Streufert, Ph.D.
Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5E03
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the Division of Scientific Review, National Institute of Child Health and Human Development (NICHD) and the National Institute of Neurological Disorders and Stroke (NINDS). Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NICHD and NINDS staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

The review criteria to be used are generally the same as for unsolicited grant applications. The NIH will administratively withdraw from competition those applications judged to be noncompetitive, and notify the applicant and institutional business official. Those applications judged to be competitive will undergo further scientific merit review by an initial review group convened by NICHD and NINDS. The second level of review will be provided by the National Advisory Child Health and Human Development and National Advisory Neurological Disorders and Stroke Councils.

INQUIRIES

Applications relevant to Sudden Infant Death Syndrome will have primary assignment to the National Institute of Child Health and Human Development. Applications to further delineate the parameters and pathophysiology of fetal brain maldevelopment and injury will have primary assignment to the National Institute of Neurological Disorders. Applications regarding the development of diagnostics to identify infants who could benefit from neonatal therapeutic strategies to prevent initiation or progression to brain injury will have primary assignment to either the National Institute of Child Health and Human Development or the National Institute of Neurological Disorders and Stroke.

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Marian Willinger, Ph.D. or Linda Wright, M.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 4B03
Bethesda, MD 20892
Telephone: (301) 496-5575

Giovanna Spinella, M.D.
Division of Convulsive, Developmental and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C-10
Bethesda, MD 20892
Telephone: (301) 496-5821

Direct inquiries regarding fiscal matters to:

Mr. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-1303

Mr. King P. Bond Jr.
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 10004
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.365, (Research for Mothers and Children), and No. 93.853, Clinical Research Related to Neurological Disorders and 93.854, Biological Basic Research in the Neurosciences. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SYMPTOM MANAGEMENT OF PERSONS INFECTED WITH HIV

NIH GUIDE, Volume 23, Number 5, February 4, 1994

RFA AVAILABLE: NR-94-004

P.T. 34; K.W. 0715008, 0730050, 0785130

National Institute of Nursing Research

Letter of Intent Receipt Date: April 5, 1994
Application Receipt Date: May 6, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Nursing Research (NINR) invites applications for preliminary investigations that will lead to large-scale clinical studies of interventions to improve the care of individuals infected with the HIV virus. The purpose of this research initiative is to lay the foundation from which intervention strategies can be tested to alleviate the physical symptoms associated with HIV infection and its treatment, prolong the symptom-free period of HIV infection, and improve the quality of life of persons living with AIDS.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Symptom Management of Persons Infected with HIV, is related to the priority areas of HIV infection and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the

Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (Oct 1, 1990). The total project period for applications submitted in response to the present RFA may not exceed three years. The anticipated award date is September 30, 1994. Awards will be limited to \$100,000 in total costs (combined direct and indirect costs) for each funding year. This RFA is a one-time solicitation for applications for new awards. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$600,000 in total costs for the first year will be committed to fund applications submitted in response to this RFA. It is anticipated that six applications will be funded. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NINR, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this research initiative is to lay the foundation from which intervention strategies can be tested to alleviate the physical symptoms associated with HIV infection and its treatment, prolong the symptom-free period of HIV infection, and improve the quality of life of persons living with AIDS. Research should focus on problems refractory to, or incompletely relieved by, medical intervention, as well as development of strategies to ameliorate the physical symptoms that are secondary to the medical management of HIV infection. To be responsive to this initiative, research concerning quality of life issues with persons infected with HIV should focus on the role of physical symptoms. Behavioral intervention strategies may be tested to alleviate physical symptoms, prolong symptom-free intervals of HIV infection or improve quality of life; however, outcome measures must include physiological responses to these interventions. Although the primary focus is on nonpharmacologic interventions, research is also needed that addresses the multimodal treatment approaches including, but not limited to, pharmacological interventions for managing symptoms. Studies addressing only pharmacological interventions will not be considered as responsive to this RFA.

Applications are invited for support of projects to address issues including, but not limited to:

- o the development of nonpharmacologic or multimodal management strategies to alleviate the physical symptoms associated with HIV infection, its complications and its treatment.
- o the identification of underlying factors that explain differential responses to clinical conditions and treatment regimens and methods to address these factors.
- o the development or refinement of instruments to assess physical symptoms and monitor changes resulting from interventions to alleviate these symptoms, if such instruments are not currently available.
- o careful scientific observations of the natural history or clinical course of physical symptoms occurring during the progression of HIV infection and its treatment if such observation is needed to adequately identify variables that can be clinically manipulated to reduce the severity or impact of those symptoms.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 5, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NINR staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Ernest Marquez
Office of Review
National Institute of Nursing Research
Westwood Building, Room 740
Bethesda, MD 20892
Telephone: (301) 594-7865

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). Application kits are available from most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The RFA label

available in the application form PHS 398 must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA and the NRCC guidelines.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NINR in accordance with the usual NIH peer review procedures. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant. Applications may be triaged by an NINR peer review group on the basis of relative competitiveness. Those applications judged to be non-competitive for award will be withdrawn and the applicant notified. Those applications judged to be competitive will undergo further scientific merit review. The review criteria are set forth in the RFA. Questions concerning the responsiveness of proposed research to the RFA may be directed to program staff listed under INQUIRIES. The second level of review will be provided by the National Advisory Council for Nursing Research.

INQUIRIES

Telephone requests for the RFA may be made to the Office of Information and Legislative Affairs, NINR, (301) 496-0207. Written and telephone inquiries concerning the objectives and scope of this RFA are welcomed. Direct written requests for the RFA and all inquiries regarding programmatic issues to:

June R. Lunney, Ph.D., R.N.
Acute and Chronic Illness Branch
National Institute of Nursing Research
Westwood Building, Room 752
Bethesda, MD 20892
Telephone: (301) 594-7397

For administrative and fiscal matters contact:

Sally A. Nichols
National Institute of Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 594-7498

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.361 Nursing Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Health Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DEVELOPMENTAL DISABILITIES PREVENTION RESEARCH CENTER

NIH GUIDE, Volume 23, Number 5, February 4, 1994

RFA AVAILABLE: HD-94-014

P.T. 34; K.W. 0775000, 0745027, 0715130

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: March 31, 1994

Application Receipt Date: May 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The budget appropriation report language for the National Institute of Child Health and Human Development (NICHD) for fiscal year 1994 indicated that funds were provided to establish "... a Developmental Disabilities Prevention Research Center within a university affiliated program (UAP), which shall investigate the critical problems of prevention and amelioration of mental retardation, specifically including: a specialized research center engaged in the multidisciplinary analysis of myelinogenesis as a critical period that is highly vulnerable to nutritional status during fetal and postnatal brain development." In response to this Congressional mandate, the Mental Retardation and Developmental Disabilities Branch (MRDD), Center for Research for Mothers and Children (CRM), NICHD, invites applications for a specialized research center that will develop new knowledge concerning diagnosis, prevention, treatment, and amelioration of mental retardation and developmental disabilities, with special emphasis on vulnerable periods in fetal and postnatal brain development. One specialized center may be supported in response to this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Developmental Disabilities Prevention Research Center, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington,

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, and units of State or local governments, provided they have an existing University Affiliated Program (UAP). Public Law 88-164, Title I, Part B authorized construction of University Affiliated Facilities, "for the purpose of assisting in the construction of clinical facilities, providing, as nearly as practicable, a full range of inpatient and outpatient services for the mentally retarded and facilities which will aid in demonstrating provision of specialized services for the diagnosis and treatment, education, training, or care of the mentally retarded or in the clinical training of physicians and other specialized personnel needed for research, diagnosis and treatment, education, training, or care of the mentally retarded..."

Applicants to this RFA may collaborate, through consultation or contractual arrangements, with foreign investigators. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH Specialized Center grant mechanism (P50). The applications should be prepared in a manner consistent with the information presented in the publication, National Institute of Child Health and Human Development, Research Center Programs which is available from the NICHD office listed below. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to this RFA may not exceed five years. The anticipated date of award is September 30, 1994.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

Applications submitted in response to this RFA will compete for \$600,000 in direct costs that will be made available for the first year of support. Only one award will be made.

RESEARCH OBJECTIVES

The MRDD Branch supports research that relates to the biological, behavioral, and social processes that contribute to, or influence the development of, mental retardation and developmental disabilities. Prevention of MRDD, and amelioration of the clinical manifestations of those afflicted, constitute areas of special emphasis within the Branch. To accomplish its mission, the MRDD Branch provides financial support for research grants, core facilities in the Mental Retardation Research Centers, specialized research centers, research contracts for the development of research resources, and for dissemination of information to the scientific community and the public.

This RFA solicits applications that will contribute to a better understanding of the causes, diagnosis, prevention, treatment and amelioration of mental retardation and developmental disabilities. The NICHD encourages basic and clinical research, using animal models and human subjects, addressing genetic, environmental and other factors that affect brain development. Research on the effects of malnutrition (protein, calorie, trace metals, vitamins), on myelinogenesis is of particular interest. Research projects on the effects of various types of intervention strategies, including nutritional supplementation, on neuropsychological development, are also encouraged.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 31, 1994, a letter of intent that includes a descriptive title of the proposed research, address and telephone number of the Principal Investigator, titles of the component subprojects and the principal investigator, core facilities, when applicable, and the director of each core, names of other key personnel and participating institutions; and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to Dr. Felix F. de la Cruz at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted using PHS 398 (rev. 9/91). Application kits containing this form and the necessary instructions are available in most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the

face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Susan Streufert, Ph.D.
Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5E-03
Bethesda, MD 20892

Applications must be received by May 18, 1994. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG, and responsiveness to the RFA by NICHD staff. Incomplete applications will be returned to the applicant without further consideration. Applications may be subjected to triage if the number of applications is large compared to the number of awards to be made. If so, the NIH will withdraw from further competition those applications judged to be non-competitive for an award and notify the applicant Principal Investigator and institutional official. Applications judged to be competitive will undergo further scientific merit review. Applications that are complete and responsive will then be evaluated for scientific and technical merit by a review panel convened solely for this purpose by the Division of Scientific Review, NICHD. The second level of review will be provided by the National Advisory Child Health and Human Development Council. Additional review criteria are listed in the RFA.

AWARD CRITERIA

In addition to the scientific and technical merit of the application, the following factors will be considered in making an award:

- o relevance to mental retardation;
- o access to unique populations; and
- o institutional commitment and support.

The anticipated date of award is September 30, 1994.

INQUIRIES

Written and telephone requests for the RFA, and the opportunity to clarify any issues or questions from potential applicants are welcome.

Requests for the RFA, NICHD Research Center Programs guidelines, and inquiries regarding programmatic, technical, and scientific issues, may be directed to:

Felix F. de la Cruz, M.D., M.P.H.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 4B-09
Bethesda, MD 20892
Telephone: (301) 496-1383

Inquiries regarding fiscal and administrative issues may be directed to:

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A-17
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MARC FACULTY RESEARCH FELLOWSHIPS

NIH GUIDE, Volume 23, Number 5, February 4, 1994

PAR NUMBER: PAR-94-032

P.T. 22, FF; K.W. 0720005

National Institute of General Medical Sciences

Application Receipt Dates: April 5 and December 5

The Minority Access to Research Careers (MARC) Program of the National Institute of General Medical Sciences (NIGMS) provides research training opportunities for faculty and students at four-year colleges that have a substantial enrollment of students from underrepresented minority groups. As part of its ongoing commitment towards enhancing the research and research training environment at these colleges, NIGMS provides support for faculty at these institutions to enhance their research skills. This announcement describes the newly revised MARC Faculty Fellowship Programs. A separate announcement, which will be published shortly will describe a new research opportunity, the MORE Faculty Development Award from the NIGMS Minority Opportunities for Research (MORE) Branch.

The Faculty Fellowship Programs provide support for two types of training for eligible faculty. The first, predoctoral training using the individual Faculty Fellowship Award, provides support for training leading to the Ph.D. for those faculty who do not have a research doctorate (i.e., Ph.D. or equivalent). The second is designed for faculty with the doctorate who are able to spend a full academic year or more in full-time training away from the home institution and uses the Senior Fellowship Award.

Faculty members who are recent recipients of the doctoral degree are encouraged to apply for the regular Postdoctoral Fellowship Award (F32) or to seek support at institutions with Institutional Postdoctoral Training Grants; there is no special MARC postdoctoral training program for these individuals. Information about these fellowships and training grants may be obtained from the relevant NIH Institute.

ELIGIBILITY REQUIREMENTS

Both types of training have the following common requirements. In addition, each mechanism has its own specific requirements described below under the appropriate heading.

In addition to the three letters of reference, the applicant should include a letter of support from his/her department chairman and signed by the Dean and other appropriate institutional officials describing the institution's commitment to the candidate. This may be included in the same letter described under "Research and Training Objectives" above.

A candidate must:

- o be full-time, permanent faculty in biomedically-related science or mathematics at the home institution for at least three years at the time of submission of the application; (Note, permanent does not mean tenured or tenure-track but implies the expectation of continued employment in the normal course of events. Adjunct or part-time faculty are not eligible.)
- o intend to return to the home institution at the end of the training period;
- o demonstrate a commitment to research and teaching in a minority institution;
- o be seeking training in a science (including mathematics) related to biomedical or behavioral research; AND
- o be a citizen or a non-citizen national of the U.S., or have been lawfully admitted for permanent residence in the U.S., at the time of application.

The home institution is the college or university where the candidate is employed at the time of the application. The home institution must:

- o be a domestic private or public minority institution, that is, one with a significant enrollment of underrepresented minorities. For purposes of this announcement, underrepresented minorities are individuals belonging to racial/ethnic groups underrepresented in the biomedical or behavioral sciences. Nationally, these groups include African Americans, Hispanic Americans, Native Americans, and Pacific Islanders. Institutions must document eligibility by providing appropriate enrollment data.
- o offer at least the baccalaureate degree in the biomedical or behavioral sciences or mathematics;
- o support the candidate's plans for training; AND
- o guarantee and provide appropriate release time for faculty for research training.

The training institution is the research university or research institution/center at which the training takes place. It may be a public or private, domestic or foreign institution. The training institution:

- o must offer a solid research environment as evidenced by a high-level of faculty involvement in biomedical research and a high-level of research support through competitive grants (or similar quality-based support, such as Howard Hughes Medical Institute support); AND
- o may NOT be the candidate's home institution.

In addition, the sponsor, who will direct the candidate's research, must be a faculty member (or equivalent) at the training institution and should have a distinguished record of achievement in research documented by high quality research publications and/or competitive research grant support.

RESEARCH OBJECTIVES

The purpose of the MARC Faculty Fellowship Program is to enhance the research and research training capabilities of the home institution by offering faculty the opportunity to obtain training for the research doctorate OR, for those faculty with doctorates, to update or enhance their research skills through high quality research experiences. The expectation is that this training will enable the faculty to be better researchers, mentors, trainers and role models in the home institution.

The application must contain a letter signed by appropriate officials of the HOME INSTITUTION, including the candidate's department head, (1) supporting the candidate's training plans; (2) guaranteeing the necessary release time for the candidate; (3) certifying the candidate's eligibility for the program; and (4) establishing the institution's eligibility as a minority institution through enrollment data.

Specific objectives for each component are discussed under the individual descriptions below.

APPLICATION PROCEDURES

Applicants for Predoctoral (F34) or Senior (F33) Fellowships must use the Individual National Research Service Award form PHS 416-1 (rev. 10/91). These forms are available in most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIGMS MARC Program Office at the address listed under INQUIRIES.

Submit a signed, typewritten original of the application, including the Checklist, and two photocopies of the signed application in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications will be accepted for the April 5 and December 5 fellowship receipt dates ONLY. They will not be accepted for the August receipt date.

In item 3, applicants must give the Program Announcement number, PA-94-032; in item 2, give the name of the appropriate MARC Faculty Fellowship Program.

REVIEW CONSIDERATIONS

Applications will be evaluated in accordance with the criteria stated below for scientific, technical and training merit by appropriate peer review groups. The second level of review will be provided by the senior staff in NIGMS. It is critical that the application contain sufficient information about each of these elements to enable the reviewers to make a reasoned evaluation.

Review criteria

- o quality and appropriateness of the proposed research training, including the specific research proposal;
- o quality of the training environment, including, but not limited to, the qualifications and grant support of the sponsor;
- o appropriateness of the plans to use the research training to enhance the research and research training capabilities of the home institution;
- o commitment of the candidate to a career in research and teaching at a minority institution;
- o strength of the support for the candidate's training by the home institution;
- o commitment of the sponsor and training institution to the candidate's training.

MARC PREDOCTORAL FACULTY FELLOWSHIP

The purpose of this program is to strengthen the research and research training opportunities of minority institutions by providing an opportunity for eligible faculty who lack the Ph.D. degree (or equivalent) to obtain the research doctorate. The expectation is that the candidate's training in a setting away from the home institution will expose the candidate to new ideas and will enhance the research and teaching environment of the home institution when the candidate returns.

Specific Eligibility

In addition to the general eligibility requirements described above, at the time of application, the candidate must be enrolled in OR have been accepted by and agreed to enroll in a Ph.D. or combined M.D./Ph.D. (or other combined professional doctorate/Ph.D.) training program in the biomedical or behavioral sciences.

MECHANISM OF SUPPORT

Awards under this program will use the faculty fellowship (F34) award. Applicants may request up to five years of support. Applications must be prepared on PHS 416-1 (rev. 10/91), National Research Service Award Application Form. In item 2 of the face page of the application, the applicant must type "MARC PREDOCTORAL FACULTY FELLOWSHIP."

The sponsoring institution will be the TRAINING INSTITUTION.

Allowable Costs

An applicant may request ONLY the following: a stipend equal to the actual annual salary but not to exceed the stipend of a level 1 postdoctoral fellow (currently \$19,700); tuition and fees as determined by the training institution; and

an institutional allowance of \$2000 per year to be used for costs directly related to the candidate's training. Funds will not be provided for purchasing equipment, although the institutional allowance may be used for this purpose PROVIDED that the equipment is DIRECTLY related to the candidate's training. No indirect costs will be paid.

The candidate's stipend may be supplemented by either the home institution or the training institution using funds from non-Federal sources only.

Additional Information

In addition to the three letters of reference, the applicant should include a letter of support from his/her department chairman and signed by the Dean and other appropriate institutional officials describing the institution's commitment to the candidate. This may be included in the same letter described under "Research and Training Objectives" above.

If, at the time of application, the candidate has selected a research thesis advisor, that individual should serve as the sponsor. If a candidate has not yet selected a research thesis advisor, the head of the graduate program should nominate someone to serve as the candidate's sponsor. The application should indicate clearly that this is an interim arrangement and should describe procedures for selecting a permanent research thesis advisor.

MARC SENIOR FACULTY FELLOWSHIP

The purpose of this program is to allow eligible faculty of minority institutions the opportunity to update their research skills and/or move into new areas of research through a year-long period of intensive research in a state-of-the-art research environment. The faculty member would have only minimal responsibilities at the home institution during the training period. The expectation is that these new skills will enhance the research and teaching environment of the home institution.

Specific Eligibility

In addition to the general eligibility requirements, at the time of application, at least 7 years must have elapsed since the candidate received the Ph.D. degree or equivalent research or professional doctorate.

Mechanism of Support

Awards under this program will use the senior fellowship (F33) award. Applicants may request no less than one academic year (9 months) and no more than two years of support. Applications must be prepared on PHS 416-1 (rev. 10/91), National Research Service Award Application Form. In Item 2 of the face page of the application, the applicant must type "MARC SENIOR FACULTY FELLOWSHIP."

The sponsoring institution will be the TRAINING INSTITUTION.

Allowable Costs

An applicant may request a stipend equal to the actual annual salary, but not to exceed the stipend of a level 7 postdoctoral fellow (currently \$32,300); the actual amount of the stipend awarded will be prorated by the length of the award if the award is for less than 12 months. An applicant may also request an institutional allowance of \$3000 per year to be used for expenses directly related to the candidate's training. No funds will be provided for purchasing equipment, travel or housing. However, the institutional allowance may be used for equipment or travel to a scientific meeting provided that these are DIRECTLY related to the candidate's training. No indirect costs will be paid.

The candidate's stipend may be supplemented by either the home institution or the training institution using non-Federal sources of funds only.

Payback

Fellows will incur a payback obligation during the first 12 months of training, which can be satisfied on a month-by-month basis either by additional research training or by resuming a career in research or teaching. See the NIH Guide for Grants and Contracts, Vol. 22, No. 27, July 30, 1993, for more details.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and institutional eligibility to:

Dr. Yvonne Maddox
Minority Access to Research Careers Program
National Institute of General Medical Sciences
Westwood Building, Room 950
Bethesda, MD 20892
Telephone: (301) 594-7823

Direct inquiries regarding fiscal matters to:

Ms. Toni Holland
National Institute of General Medical Sciences
Westwood Building, Room 935
Bethesda, MD 20892
Telephone: (301) 594-7819

CULTURALLY SENSITIVE INTERVENTION STRATEGIES FOR PROMOTING OR IMPLEMENTING COMPLIANCE WITH NCI DIETARY GUIDELINES AMONG AFRICAN AMERICANS

NIH GUIDE, Volume 23, Number 5, February 4, 1994

PA NUMBER: PA-94-033

P.T. 34, FC; K.W. 0710095, 0715035, 0502017

National Cancer Institute

PURPOSE

The National Cancer Institute (NCI) invites applications for studies to develop and evaluate the effectiveness of culturally sensitive intervention strategies to assist African Americans in adopting eating patterns consistent with the NCI Dietary Guidelines.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Culturally Sensitive Intervention Strategies for Promoting or Implementing Compliance with NCI Dietary Guidelines Among African Americans, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by non-profit and for-profit organizations and by public and private entities such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the federal government. Applications from minority investigators and women are encouraged. Foreign organizations are ineligible to apply.

MECHANISM OF SUPPORT

Support mechanisms for this program announcement will be the research project grants (R01) and First Independent Research Support and Transition (FIRST) Award (R29). Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of an award will vary also.

RESEARCH OBJECTIVES

Epidemiological as well as laboratory evidence over the past 20 years indicates significant correlations between diet and specific cancers, including breast, colorectal, prostate, oral cavity, stomach, esophageal, and possibly lung. It has been estimated that 35 percent (10 to 70 percent) of all cancer deaths may be attributed to diet.

The NCI dietary guidelines suggest dietary changes that may decrease an individual's risk for cancer. This concept addresses three of the NCI dietary guidelines: (a) Reduce fat intake to 30 percent or less of calories; (b) Increase fiber intake to 20 to 30 grams daily, with an upper limit of 35 grams; and (c) Include a variety of vegetables and fruits in the daily diet. The NCI dietary guidelines for cancer prevention are relevant to several of the national health promotion and disease prevention objectives for nutrition and cancer reduction outlined in the Healthy People 2000 report (1990).

Comparison of African Americans' dietary intake patterns to the NCI guidelines indicate deficiencies. For example, the daily fat intake among African Americans in two studies was 36.0 percent of kilocalories. The mean daily intake of fiber was 8.0 grams for African American females. They were eating less than three servings of vegetables daily. In addition, they were consuming less than two servings of fruits and juices.

Conventional dietary and weight change programs are not well suited to the special needs of African Americans because they neglect to incorporate relevant cultural features. Cultural variables are seldom considered in behavioral change program design and implementation. However, culture influences various aspects of life, including food preferences and ideas about disease causation. But, few conventional weight loss and dietary change programs have considered African Americans' special needs.

This program announcement has four major research objectives: (1) To identify barriers and motivators of dietary change among African Americans; (2) To develop culturally sensitive intervention strategies to increase knowledge and promote attitude and dietary/behavior change among African Americans; (3) To evaluate the effectiveness of these culturally sensitive dietary/behavior intervention strategies on achievement and adherence to the NCI dietary guidelines; and (4) To examine the effect of dietary changes on selective biochemical and anthropometric parameters, such as serum lipids, estradiol, body mass index, and waist to hip ratio. Investigators will be encouraged to summarize and publish process and outcome results from these studies for use by community-level organizations that serve African Americans. Intervention sites may include, but are not limited to, various African American religious, professional, medical/nursing, social, public housing organizations, and community health centers as well as worksites, and businesses. Interventions may target individuals, households, groups, and/or organizations. Two types of evaluation should take place under this PA: (1) process evaluation to identify ways of improving the program and determine how much of the program is being implemented as planned; and (2) outcome evaluation to judge how effectively the intervention strategies have worked. Investigators will be required to provide full details of how they intend to accomplish these types of evaluation, and how they will recruit and retain study subjects. A variety of culturally sensitive intervention strategies rather than a single approach should be used and should be adapted to the special needs of African Americans to provide them with the skills they need to make dietary change. Multidisciplinary teams are encouraged to apply.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies or etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials. The usual policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning a priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATIONS PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following study section review, the applications will receive a second-level review by an appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other applications assigned to that ICD and recommended for further consideration. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Jacqueline Whittted, Ph.D.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 232
Bethesda, MD 20892-4200
Telephone: (301) 496-8584

Direct inquiries regarding fiscal matters to:

Kathleen Shino
Division of Grants Administration
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892-4200
Telephone: (301) 496-7800 ext. 48

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***

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NIH GUIDE

For Grants and Contracts

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FEB 23 1994

National Institutes of Health

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

RICHARD W MURRY

340189
51350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3269

Vol. 23, No. 7
February 18, 1994

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NOTICES

PURCHASE OF EQUIPMENT AND PRODUCTS UNDER NIH ASSISTANCE AWARDS - BUY AMERICAN PROVISIONS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

P.T.

National Institutes of Health

The National Institutes of Health (NIH) Revitalization Act (P.L. 103-43, June 10, 1993) places certain requirements on recipients of assistance with respect to the purchase of equipment and supplies. Specifically, section 2004 (Buy American Provisions) requires that if any equipment or product is authorized to be purchased with financial assistance provided pursuant to this Act for any of the fiscal years 1994 through 1996, entities receiving such assistance should, in expending the assistance, purchase only American-made equipment and products. Section 2004 further requires the Secretary of Health and Human Services, in providing financial assistance pursuant to this Act, to provide each recipient of the assistance a notice describing the above statement, made by the Congress.

Thus, recipients of NIH assistance awards (including those subcontracts for substantive programmatic work under NIH assistance awards) are strongly encouraged, when purchasing equipment and products, to expend the assistance for American-made equipment and products, whenever possible. Beginning in fiscal year 1994, notices of grant and fellowship award will include a footnote containing the following language:

"Pursuant to the NIH Revitalization Act (P.L. 103-43, June 10, 1993), section 2004, when purchasing equipment or products under this assistance award, the recipient should, whenever possible, purchase only American-made items."

If you have any questions concerning this policy, contact the NIH grants management contact listed on the notice of grant or fellowship award.

DISCONTINUATION OF THE CNRS POSTDOCTORAL FELLOWSHIPS PROGRAM

NIH GUIDE, Volume 23, Number 7, February 18, 1994

P.T. 34; K.W. 1014006

Fogarty International Center

The Fogarty International Center (FIC) announces that it is no longer accepting applications for the Centre National de la Recherche Scientifique/National Institutes of Health Postdoctoral Fellowships (CNRS/NIH - F07) program.

Please note that this change is effective as of the date of this publication; therefore, applications for this program will not be accepted for the April 5, 1994 receipt date.

INQUIRIES

For further information, contact:

CNRS/NIH Fellowship Program
International Research and Awards Branch
Fogarty International Center
Building 31, Room B2C39
Bethesda, MD 20892
Telephone: (301) 496-1653
Fax (301) 402-0779

SALARY LIMITATION ON GRANTS AND CONTRACTS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

P.T.

National Institutes of Health

The purpose of this notice is to provide updated information regarding the salary limitation as it relates to NIH grant and cooperative agreement awards (hereafter called 'grant'). This information also applies to extramural research and development contract awards. In addition, this notice describes a change in the way that NIH Institutes and Centers (I/Cs) are treating salaries in excess of the limit for any future years in competing grant awards. The last notice in the NIH Guide for Grants and Contracts regarding the salary limitation was in Vol. 20, No. 47, December 20, 1991.

Fiscal Year (FY) 94 is the fifth consecutive year for which there is a legislatively mandated provision for the limitation of salary. Specifically, the Department of Health and Human Services (HHS) Appropriations Act for FY 94, Public Law 103-112, restricts the amount of direct salary an individual under a grant or applicable contract issued by the NIH to a RATE of \$125,000 per year. Direct salary is exclusive of fringe benefits and indirect costs/general and administrative expenses. The salary limit of \$125,000 has not increased from the FY 93 level.

The NIH will continue to apply the limits to all grant and applicable contract awards and all funding amendments to existing awards made with FY 94 funds. Therefore, NIH grant and applicable contract awards for applications/proposals that request direct salaries of individuals in excess of a RATE of \$125,000 per year will be adjusted in accordance with the legislative salary limitation, and will include a notification such as:

According to the HHS Appropriations Act, "None of the funds appropriated in this title for the National Institutes of Health . . . shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of \$125,000 per year."

The following are examples of the adjustments that NIH will make when salaries exceed the limit:

EXAMPLE 1. INDIVIDUAL WITH FULL-TIME APPOINTMENT.

| | |
|--|-----------|
| Individual's institutional base* salary for a FULL-TIME (twelve month) appointment | \$150,000 |
| Research effort requested in application/ proposal | 50% |
| Direct Salary requested | \$75,000 |
| Fringe benefits requested (25% of salary) | \$18,750 |
| Subtotal | \$93,750 |
| Applicant organization's indirect costs at a rate of 45% of subtotal | \$42,188 |
| Amount requested - salary plus fringe benefits plus associated indirect costs | \$135,938 |

If a grant/contract is to be funded, the amount included in the award for the above individual will be calculated as follows:

| | |
|---|-----------|
| Direct salary - restricted to a RATE of \$125,000 multiplied by effort (50%) to be devoted to project | \$62,500 |
| Fringe benefits (25% of allowable salary) | \$15,625 |
| Subtotal | \$78,125 |
| Associated indirect costs at 45% of subtotal | \$35,156 |
| Total amount to be awarded due to salary limitation | \$113,281 |

| | |
|---|----------|
| Amount of reduction due to salary limitation (\$135,938 requested minus \$113,281 awarded) | \$22,657 |
|---|----------|

* An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization.

EXAMPLE 2. INDIVIDUAL WITH HALF-TIME APPOINTMENT.

| | |
|--|----------|
| Individual's institutional base salary for a HALF-TIME appointment (50% of a full-time twelve month appointment) | \$65,000 |
| Research effort requested in application/ proposal | 30% |
| Direct Salary requested | \$19,500 |
| Fringe benefits requested (25% of salary) | \$4,875 |
| Subtotal | \$24,375 |
| Applicant organization's indirect costs at a rate of 45% of subtotal | \$10,969 |
| Amount requested - salary plus fringe benefits plus associated indirect costs | \$35,344 |

If a grant/contract is to be funded, the amount included in the award for the above individual will be calculated as follows:

| | |
|--|----------|
| Direct salary - restricted to a RATE of | |
| \$125,000 multiplied by 50% appointment by | |
| 30% effort to be devoted to project | \$18,750 |
| Fringe benefits (25% of allowable salary) | \$4,688 |
| Subtotal | \$23,438 |
| Associated indirect costs at 45% of subtotal | \$10,547 |
| Total amount to be awarded due to salary | |
| limitation | \$33,985 |

| | |
|--|---------|
| Amount of reduction due to salary limitation | |
| (\$35,344 requested minus \$33,985 awarded) | \$1,359 |

Other important points relating to both NIH grants and contracts are:

- o An individual's base salary, per se, is NOT constrained by the legislative provision for the limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to NIH grant and applicable contract awards. An institution may supplement an individual's salary with non-federal funds.

- o The salary limitation does NOT apply to payments made to consultants under an NIH grant or contract although, as with all costs, such payments must meet the test of reasonableness.

- o The salary limitation provision DOES apply to those subawards/subcontracts for substantive work under an NIH grant or contract.

In addition, the following three paragraphs apply to GRANT applications/awards only:

- o COMPETING grant applications submitted to the NIH may continue to request funding at the regular/actual rates of pay of all individuals for whom reimbursement is requested, even when these rates exceed the salary limitation. NIH staff will make necessary adjustments to requested salaries prior to award.

- o There is a change in the way that NIH I/Cs are treating salaries in excess of the limit for any FUTURE years beginning with COMPETING grant awards funded with FY 94 funds. Based upon experience and the expectation that the salary restriction will continue in future appropriations (although the amount of the limitation may change with future appropriations), NIH awards for COMPETING applications will reflect adjustments to all years of a project, including future years, so that no funds are awarded or committed for salaries over the limitation.

- o With regard to NON-COMPETING continuation grant applications submitted to NIH, these applications should request funds for salaries at rates of pay that DO NOT exceed the salary limitation. If the current committed level includes funds for salaries at a rate that exceeds the salary limitation, the excess may not be rebudgeted for any other purpose, and NIH staff will delete it from the award.

For further information concerning policies relating to grants or contracts, contact any of the grants management offices and/or contracts management offices of the NIH funding components.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MAMMALIAN GENOTYPING SERVICE

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFP AVAILABLE: NIH-NHLBI-HV-94-14

P.T.

National Heart, Lung, and Blood Institute

The Hypertension and Kidney Diseases Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) has a requirement for the establishment of a large-scale genotyping service capable of genotyping large numbers of human and mammalian DNA samples as a cost-effective means to reliably and efficiently facilitate identification of genes responsible for cardiovascular, pulmonary and hematologic diseases. The genotyping service is to utilize polymerase chain reaction (PCR)-based techniques to provide highest quality genotypes and operate on a fee-for-service basis. Automated methods and robotics are required. The service will not isolate genomic DNA from tissues and cells, but must provide storage of the DNA, which will be provided by users of the service. Genotypic data will be provided to users of this service as hard-copies (e.g., graphs, photographs, autoradiographs) and on computer disc, where it must be compiled into simple software programs for use in more than one of the commonly used personal computing systems utilized by scientists. The service is to focus on production of samples and is expected in subsequent years to increase production capacity, while reducing the fee-for-service. Since other funding mechanisms are currently available to support the development of new technologies and methodologies to improve genotyping speed, quality, and cost, no funds will be available for this explicit purpose in the contract. However, the service is responsible for incorporating any applicable, newly developed technologies, methodologies, and their refinements, into the existing structure in subsequent years to improve genotyping quality, to decrease costs and to increase the production of genotypes. Genotyping projects will be submitted to the service, wherein a review panel of scientific experts, established and coordinated by the Contractor, will assess the scientific merit, feasibility, cost and, in conjunction with the NHLBI, programmatic relevance. In order to ensure that the service has sufficient work, projects outside of NHLBI programmatic relevance will be considered for genotyping. However, meritorious projects with NHLBI programmatic relevance will receive priority over projects supported through other sources.

The purpose of this contract is to provide seed money for the establishment of the genotyping service. It will provide decreasing funds over a five-year period in order to allow for the service to become fully established, while maintaining itself by fee-for-service. Prospective offerors should have well-recognized expertise and experience in genomics, molecular genetics, informatics, robotics, and molecular biology. In particular, offerors should have experience in PCR-based methods to map genes. A single multi-year incrementally funded award is anticipated. RFP NIH-NHLBI-HV-94-14 will be released on or about February 18, 1994.

INQUIRIES

To receive a copy of the RFP, include three labels self-addressed with your mailing address and must cite RFP No. NIH-NHLBI-HV-94-14. Requests for copies of the RFP are to be sent to:

Shari L. Spencer
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 4C04
Bethesda, MD 20892

PHASE II CLINICAL TRIALS OF NEW CHEMOPREVENTIVE AGENTS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFP AVAILABLE: NCI-CN-45593-32

P.T.

National Cancer Institute

The National Cancer Institute (NCI) is seeking contractors qualified to perform Phase II Clinical Trials that are small short-term, efficient studies of potential chemopreventive agents. This work includes small, short-term, efficient studies to determine the dose of a given chemopreventive agent that exhibits a pharmacodynamic effect on an intermediate endpoint. These studies will also require dose response studies to determine the minimum dose at which a biological effect is observed and confirmation of the maximum safe dose, and the performance of randomized blinded trials in small groups of subjects whose endpoints will be the measurable biological effect of the agent versus a placebo. This solicitation is an annual announcement to expand a current pool of Master Agreement (MA) Holders qualified to perform this type of work. Individual work requirements will be defined, as the need arises, by Master Agreement Orders issued during the period of performance, and Master Agreement Orders will be awarded based on competition between members of the MA pool. The solicitation will be released on or about February 22, 1994, with proposals due April 22, 1994.

INQUIRIES

The Contracting Officer for this solicitation is Richard L. Hartmann on telephone (301) 496-8603. Copies of the RFP may be obtained by sending a written request to:

Ms. Desiree Sylver-Foust
Research Contracts Branch
National Cancer Institute
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

PRECLINICAL EVALUATION OF INTERMEDIATE ENDPOINTS AND THEIR MODULATION BY CHEMOPREVENTIVE AGENTS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFP AVAILABLE: NCI-CN-45594-32

P.T. 34; K.W. 0715035, 0755020, 0740018, 0760003

National Cancer Institute

The National Cancer Institute is seeking contractors qualified to perform animal cancer model studies of biomarkers and intermediate endpoints that might be used in human clinical trials. The work to be performed will assess, in detail, the biomarker modulating effects of selected chemopreventive compounds. This solicitation is an annual announcement to expand a current pool of Master Agreement (MA) Holders qualified to perform this type of work. Individual work requirements will be defined as the need arises by Master Agreement Orders issued during the period of performance, and Master Agreement Orders will be awarded based on competition between members of the MA pool. The solicitation will be released on or about February 22, 1994 with proposals due April 23, 1994.

INQUIRIES

The Contracting Officer for this solicitation is Richard L. Hartmann on telephone (301) 496-8603. Copies of the RFP may be obtained by sending a written request to:

Ms. Desiree Sylver-Foust
Research Contracts Branch
National Cancer Institute
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

ORAL MANIFESTATIONS OF HIV INFECTION

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFA AVAILABLE: DE-94-003

P.T. 34; K.W. 0715148, 0715008

National Institute of Dental Research

Letter of Intent Receipt Date: April 1, 1994

Application Receipt Date: May 6, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Dental Research (NIDR) invites research grant applications to support research projects on the oral manifestations of Human Immunodeficiency Virus (HIV) infection. These projects encompass multidisciplinary, basic, clinical, epidemiologic, and behavioral research designed to slow the spread of acquired immunodeficiency syndrome (AIDS), to reduce the severity of oral complications of HIV infection, and to minimize the effects of HIV therapy.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Oral Manifestations of HIV Disease, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. However, foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms available for support of applications in response to this RFA include research project grants (R01) and FIRST (R29) awards.

FUNDS AVAILABLE

The NIDR will allocate approximately \$2 million to support projects from this RFA during FY 1994. It is anticipated that at least eight awards will be made, provided that applications are of sufficient scientific merit. Applicants may request up to five years of support. Subsequent support will be dependent upon submission by the applicant of a renewal application through established NIH procedures for research grants related to AIDS. Policies that govern research grant programs of the National Institutes of Health will prevail.

RESEARCH OBJECTIVES

Background

Interest by the NIDR in AIDS, which dates back to shortly after the disease was first identified, is based primarily on the prevalence and severity of oral mucosal and gingival lesions, non-infectious oral lesions, opportunistic infections, the importance of oral fluids as sources of HIV inhibitory factors and as non-invasive diagnostic tests for HIV. In addition, two international workshops, partially supported by NIDR and devoted exclusively to the oral manifestations of HIV infection, vividly point up the need for continuing broad scale multidisciplinary studies to better understand the natural history of the HIV and its oral manifestations in order to minimize their devastating effects.

The primary goal of this initiative is to broaden the base of HIV-related research supported by the NIDR by stimulating the submission of proposals that address the full range of oral manifestations of HIV infection including basic, clinical, epidemiologic and behavioral investigations. Specifically, studies are being sought that will fully characterize HIV inhibitory factors in saliva and determine their mechanisms of action; investigate more fully the potential of saliva and other oral fluids to serve as accurate non-invasive markers of HIV infection; exploit the use of currently available techniques to explain the variable relationship between immune status, variety of periodontopathic pathogens in the oral cavity and periodontal status of HIV-positive and HIV-negative subjects; longitudinal studies of the oral side effects of HIV therapy; status of HIV-positive and HIV-negative subjects; longitudinal studies of the oral side effects of HIV therapy; studies to determine to what extent gender may influence the range and severity of HIV-associated oral lesions; and community-level intervention research aimed at prevention, maintenance of behavioral changes and social and behavioral issues in therapeutic and vaccine trials for oral lesions in HIV patients.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH policy is that applicants for clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent by April 1, 1994. The letter should include a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and their participating institution(s), and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains is helpful to the NIDR staff in planning for timely review of applications. It also allows NIDR staff to estimate the potential workload and to avoid possible conflict of interest in review.

The letter of intent is to be sent to Dr. Matthew Kinnard at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are encouraged to consider collaborative arrangement with investigators from other organizations. Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or Principal Investigator should be included with the application.

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248; and from the program administrator listed under INQUIRIES.

To identify the application as a response to this RFA, check "YES" on item 2a of face page of the application and enter RFA: DE-94-003, "Oral Manifestations of HIV Infection". The RFA label available in the form PHS 398 must be affixed to the bottom of the face page of the original application. Failure to use this label could result in delayed processing of an application such that it may not reach the review committee in time for review.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Submit a signed, typewritten original of the application, including the checklist, and three signed, photocopies, by May 6, 1994 in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must be sent to:

H. George Hausch, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 519
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NIDR program staff function. Applications that are considered non-responsive will be returned by the NIDR, but may be submitted as investigator-initiated regular research grants at the next receipt date.

Applications that are complete and responsive may be subjected to a triage by a peer review group to determine their scientific merit relative to the other applications received in response to the RFA. The NIH will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official. Applications judged to be competitive will be further evaluated for scientific/technical merit by a special grants review committee convened by the NIDR Scientific Review Office. Secondary review will be by the National Advisory Dental Research Council.

Major factors to be considered in the evaluation of applications include:

- o scientific, technical, or medical significance and originality of proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly but not exclusively in the area of the proposed research;

- o availability of resources necessary to perform research;
- o appropriateness of the proposed budget and duration in relation to the proposed research.

AWARD CRITERIA

The anticipated date of award is September 30, 1994. Applicants will compete for available funds with all other recommended applications and should be aware that, in addition to scientific merit, program priorities, program balance, the total cost of the proposed project and the availability of funds will be considered by NIDR staff and the Council in making funding recommendations. In addition, the NIDR appreciates the value of complementary funding from other public and private sources including foundations and industrial concerns.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Matthew A. Kinnard
Oral Soft Tissue Diseases and AIDS Program
National Institute of Dental Research
Westwood Building, Room 509
Bethesda, MD 20892
Telephone: (301) 594-7641
FAX: (301) 594-9720

Inquiries regarding fiscal matters may be directed to:

Ms. Theresa Ringler
Grants Management Office
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629
FAX: (301) 594-7600

Inquiries regarding review issues may be directed to Dr. George Hausch at the address listed under APPLICATION PROCEDURES.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.121. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ADOLESCENT MEDICINE HIV/AIDS RESEARCH NETWORK

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFA AVAILABLE: HD-94-012

P.T.

National Institute of Child Health and Human Development
National Institute of Allergy and Infectious Diseases
Health Resources and Services Administration

Letter of Intent Receipt Date: March 30, 1994
Application Receipt Date: May 13, 1994

THIS IS A NOTICE OF THE AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) and the National Institute of Allergy and Infectious Diseases (NIAID), in responding to identified research needs in human immunodeficiency virus (HIV)-infected and at risk adolescents (U.S. Congress, Office of Technology Assessment, Adolescent Health- Volume I; Summary and Policy Options, OTA-H-468 (Washington DC: US Government Printing Office, April 1991)) and Public Law 103-43-- National Institutes of Health Revitalization Act of 1993, Title X, Subtitle D, Section 1031--Prospective Longitudinal Study on Adolescent Health, invite applications for cooperative agreements to participate in a clinical network to plan and conduct research on the medical, biobehavioral, and psychosocial aspects of HIV/AIDS, including access to care and its utilization in adolescents infected with HIV through sexual or drug-taking behaviors. The network will initially focus on adolescents between ages 15 and 19 years and as funding becomes available expand to include adolescents between the ages of 12 and 19 years. The Maternal and Child Health Bureau (MCHB), Division of Services for Children with Special Needs (DSCSN), Health Resources and Services Administration (HRSA) will provide the funds to support clinical sites to (1) develop the comprehensive health care infrastructure necessary to support clinical research where such infrastructure does not exist

and (2) develop and disseminate treatment and policy guidelines specific to HIV-infected adolescents.

Applicants for the Basic Science Group should have research experience pertinent to the objectives delineated in this RFA. Applicants for the Clinical Science Group must provide health care services to HIV-infected adolescents. Furthermore, they must demonstrate the proven capacity to reach sufficient numbers of adolescents with HIV infection and provide comprehensive adolescent HIV-related health care and support services (Track A) or submit a plan to provide comprehensive adolescent HIV-related health care and support services in support of clinical research (Track B). In addition, applicants for either Track A or Track B in the Clinical Science Group must be willing and able to participate in a cooperative program of research and evaluation with other successful applicants. Applicants are encouraged, where appropriate, to apply as a consortium in order to satisfy site, service, and recruitment requirements. Existing and operational consortia are preferred to those convened around grant requirements. Consortia may apply in Track A or Track B. Track A consortium applicants must demonstrate the capacity for comprehensive health care services at each participating site; Track B consortium applicants must submit a plan for using limited Track B funds to provide comprehensive health care services in support of clinical research at all participating sites where such service does not exist. The network will consist of a Basic Science Group and a Clinical Science Group; applicants may apply for funding in either group component or both. Applicants to the Clinical Science Group must indicate Track A or Track B consideration.

NICHD, NIAID, and HRSA also invite applications for a cooperative agreement with a Data and Operations Center for the Network. This Data and Operations Center will manage data from surveys, studies, and interventions at the funded sites, consult on and perform the appropriate statistical analyses of the data, maintain the communications link for the network, and support the activities of research planning, protocol design, and information dissemination. This center will be functionally independent of all research sites, although it could be physically located at one of them.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Adolescent Medicine HIV/AIDS Research Network, is related to the priority areas of health and well-being of special population groups and HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Minority investigators and women are encouraged to apply. It is expected that applicants for the Basic Science Group have research experience pertinent to the objectives of the network delineated in this RFA.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U01), an "assistance" mechanism (rather than an "acquisition" mechanism) in which substantial NIH and HRSA scientific and/or programmatic involvement with the awardee is anticipated during the performance of the activity. (PHS Grants Policy Statement, DHHS (OASH) 90-50,000 (rev. October 1, 1991). Under the cooperative agreement, the purpose of the NIH and HRSA is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Specifically, members of the NICHD, NIAID, and HRSA scientific and program staff will cooperate with principal investigators as partners in the projects and serve as science collaborators or program managers. All parties will agree to accept the participatory and cooperative nature of the group process. Details of the responsibilities, relationship, and governance of the study to be funded under cooperative agreements are discussed in the RFA under the section "Terms and Conditions of Award".

The total project period for applications submitted in response to the present RFA may not exceed five years. The anticipated award date is September, 1994. At this time, NICHD, NIAID, and HRSA have not determined whether or how this solicitation will be continued beyond the present RFA.

FUNDS AVAILABLE

NIAID funds available for the support of this program are \$300,000 (total costs). The estimated NICHD funds available for support of the entire program in Phase I (consisting of six months for planning and base protocol/management guidelines development) and Phase II (consisting of the subsequent six months for protocol implementation and subject recruitment) during the first year are \$2,400,000 (total costs). These funds will support the direct cost of activities of the Basic Science Group, the clinical research activities of the Clinical Science Group, and the operations/support activities of the Data and Operations Center. Direct costs are approximated as follows:

- (1) For all non-laboratory components of the Basic Science Group - \$235,000 (direct costs) for 8-10 awards.
- (2) For the clinical research activities of the Clinical Science Group - \$875,000 (direct costs) for 8-10 awards. This amount includes subject encounter costs for two visits of the base protocol in year one for all awardees in the Clinical Science Group.
- (3) For the data operations and support services of the Data and Operations Center - \$450,000 (direct costs).
- (4) For the support of the AIDS Clinical Trials Group (ACTG)-certified virology laboratory which is part of the Basic Science Group - \$120,000 (direct costs).
- (5) For the support of the AIDS Clinical Trials Group (ACTG)-certified immunology laboratory which is part of the Basic Science Group - \$120,000 (direct costs).

In addition, the estimated HRSA funds available for support of the Track B clinical sites in Phase II and the resource capacity of the clinical sites are \$250,000 (total costs). It is expected that supplemental NIH funds will be added in future years to cover costs of full year research staff at clinical sites and special studies to be undertaken in the assembled cohort enrolled in the base protocol. Track B awards include additional HRSA money to support the health

care infrastructure in augmented service delivery in support of the clinical research agenda of the Network. It is anticipated that eight to ten Basic Science Group including one virology laboratory and one immunology laboratory, eight to ten Clinical Science Group including two to three Track B sites, and one Data/Operations Center awards will be made.

RESEARCH OBJECTIVES

This initiative calls for a descriptive examination of the full spectrum of HIV disease and its behavioral manifestations in adolescents who have become infected with HIV through sex and drug-taking behaviors in order to identify and pursue HIV/AIDS- specific research agenda in the adolescent population between the ages of 15 and 19 years of age. Adolescents between 12 and 15 years of age may be incorporated in future potential expansions of the network. The ultimate goal of this project is to achieve a better understanding of HIV disease progression and co-morbidity in adolescents and thus improve health care management. This goal will be addressed through the enrollment of approximately 200 HIV-infected adolescents into a standardized base protocol to characterize population-based spectrum of disease, disease progression, and the effect of comorbidity with other sexually-transmitted diseases and pregnancy in the adolescent population; and the standardization and evaluation of health care services. A secondary goal involves the resolution of remaining questions related to HIV infection in adolescents through the development of special studies to be undertaken in the assembled cohort enrolled in the base protocol. These unresolved questions include, but are not limited to, the susceptibility, infectivity, and transmissibility of HIV in adolescents, particularly related to developing genital mucosa; the characterization of the variation in adolescent immune function; the identification of useful adolescent-specific clinical markers of HIV disease progression; the effect of HIV on adolescent neuropsychologic function and development; and the influence and effect of specific adolescent behavioral patterns on risk-taking and health-seeking activities. The network will also produce and evaluate clinical management guidelines for adolescent HIV infection that recognize the unique biological and behavioral features of this group. The network will assist member units in establishing an interface with adolescent-eligible clinical drug and vaccine trials through a variety of mechanisms that are appropriate to the clinical research issues facing the group and that take into account particular issues facing adolescents.

SPECIAL REQUIREMENTS

The Adolescent Medicine HIV/AIDS Research Network will consist of two interactive groups, Basic Science and Clinical Science, managed by Steering and Executive Committees, supported by a Data and Operations Center, and advised by a Community Advisory Board. See the RFA for more details.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 30, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows ICD staff to estimate potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Audrey Smith Rogers at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). This application form is available in the office of sponsored research at most academic and research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda MD 20892, telephone (301) 594-7248 and from the NIH program administrator at the address listed under INQUIRIES. Applications must be received by close of business on May 13, 1994.

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an initial review group convened by the NICHD. All applications will be judged on their scientific, technical, or medical significance and originality of the proposed research; appropriateness and adequacy of the experimental approach and methodology to carry out the research; qualifications and experience of the principal investigator and staff, particularly, but not exclusively, in the area of the proposed research; availability of the resources necessary to perform the research; appropriateness of the proposed budget and duration in relation to the proposed research; appropriateness of plans for the inclusion of women and minorities as subjects; responsiveness to the goals of the RFA; and appropriateness of methods and demonstrated willingness to work as a part of the cooperative study with the NICHD, NIAID, and HRSA scientists. In addition to these general criteria, additional review criteria, set forth in the RFA, will be used in evaluating several of the components.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Two pre-submission conferences providing the same information will be held:

March 9, 1994 from 11:00 AM-12:30 PM
6100 Building, 5th Floor Conference Room
6100 Executive Boulevard
Rockville, MD 20852

March 17, 1994 from 6:30-8:00 PM
Century Plaza Hotel and Towers - Redwood Room
2025 Avenue of the Stars
Los Angeles, CA 90067-4696

Direct inquiries regarding programmatic issues and requests for the RFA to:

Audrey Smith Rogers, Ph.D., M.P.H.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Executive Boulevard, Suite 4B11
Rockville, MD 20852
Telephone: (301) 496-7339

Tina Johnson, M.A.
Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 2A09
Rockville, MD 20852
Telephone: (301) 496-8214

Direct inquiries regarding administrative/fiscal matters to:

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Suite 8A17F
Rockville, MD 20852
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

AHCPR RURAL CENTERS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFA AVAILABLE: HS-94-006

P.T.

Agency for Health Care Policy and Research

Letter of Intent Receipt Date: April 15, 1994
Application Receipt Date: May 17, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces the availability of cooperative agreements to develop and manage AHCPR Rural Centers (Centers) to plan and carry out demonstrations of rural managed care systems in HHS Regions which do not currently have an AHCPR Rural Center: Regions I, III, VI, VII, and IX. This solicitation is part of AHCPR's Rural Health Initiative. (AHCPR now supports by contracts Rural Centers in Regions II, IV, V, VIII, and X).

The Centers are encouraged to form consortia that include appropriate State health agencies and academic health science centers. Center staff should include appropriate multidisciplinary scientific and administrative experts.

This RFA responds to a Fiscal Year (FY) 1994 directive from the Senate Appropriations Committee for AHCPR to make grants or cooperative agreements to rural States or health science centers to assist in the development and demonstration of managed care networks. The Committee is particularly concerned that changes in health care systems nationally that incorporate innovations in the organization, financing, and delivery of health care services will not be as accessible to rural populations as those in urban areas where market forces already effect changes.

The Centers, with substantial input from staff and consultants at AHCPR, will conduct demonstrations of innovations in the delivery of health care services in rural areas of the Center's respective State or region. Priority will be given to demonstrations of organized networks of health services delivered to underserved populations such as populations living in a designated health professional shortage area, those living in isolated areas and/or impoverished areas, and uninsured and/or unemployed rural people. AHCPR will arrange for the conduct of independent evaluations of these demonstrations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA is related to several priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by: domestic, non-profit organizations, public or private, including universities, clinics, State and local governments, and non-profit foundations; or consortia of organizations, if the application is submitted by a domestic, non-profit, public or private organization. For AHCPR Rural Center demonstration projects, only non-profit organizations in HHS Regions I, III, VI, VII, and IX are eligible to apply. See discussion under "Objectives and Scope."

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be the cooperative agreement (U54), an assistance mechanism (rather than an acquisition mechanism), in which substantial AHCPR scientific and programmatic involvement with the awardee(s) is anticipated during the performance of the activity. The total project period for applications submitted in response to this RFA may not exceed five years. The anticipated award date is September 1, 1994. Award of funding beyond the initial budget period will depend upon availability of funds, satisfactory progress, and annual progress reviews by AHCPR. See the RFA for further explanation of the MECHANISM OF SUPPORT.

FUNDS AVAILABLE

The AHCPR expects to award a total of \$10 million over five years under this RFA for up to five applicants. Up to \$2 million will be available in FY 1994 and an average of \$2 million for each of the next four fiscal years.

RESEARCH OBJECTIVES

Overview. The Senate Committee Report on FY 1994 Appropriations directed AHCPR to "give grants or cooperative agreements to rural States or health sciences centers for planning (including an evaluation plan) and initiating a statewide or regional managed care system." The Committee states that the managed care network will be in a State that has: limited public transportation infrastructure, geographic features that limit transportation, significant health status problems in the population, limited managed care penetration statewide, unemployment rates above the national average, and a high percentage of the rural area designated as health professional shortage areas.

The RFA is for the planning and implementing of demonstration projects aimed at improving access to quality health care for rural residents, using managed care principles. These projects should be in States which reflect the criteria in the Senate Committee Report, as listed above. These demonstrations are to be performed in the context of health care reform and on a statewide or regional basis. Because the involvement of many organizations, agencies, and individuals is essential to develop viable managed care systems, participation of consortia is strongly encouraged. Consortia should include appropriate public health authorities, health care providers, and analytic and technical expertise. The establishment of Centers will strengthen the effectiveness of consortia and collaborative arrangements among State health agencies, academic health science centers, and other groups necessary to design, implement, and monitor system changes in delivery of health services in rural areas.

Objectives and Scope. As an earlier step in its Rural Health Initiative, AHCPR contracted for five AHCPR Rural Centers in FY 1993 (HHS Regions II, IV, V, VIII, and X). The RFA is aimed at addressing needs in the remaining Regions through cooperative agreements with rural States themselves, their academic health sciences centers, or other appropriate organizations. The new AHCPR Rural Centers will plan, implement, and monitor statewide managed care systems; and broadly disseminate project information and results.

Work carried out by each Center will be multidisciplinary and must address important health services delivery issues. Projects should address, as appropriate, some issues such as: arranging for primary care in rural areas; monitoring the appropriateness and effectiveness of rural health care services; expanding existing networks or developing managed care system models; and developing information networks to facilitate information transfer.

Refer to the RFA for further information on these areas and for the requirements for "Center Structure".

SPECIAL REQUIREMENTS

Terms and Conditions of Award

The awardee will determine the organization and management of the Center as specified by the RFA and retains responsibility for all aspects of performance of the Center. The AHCPR will have substantial programmatic involvement in the planning, implementation, and monitoring of demonstrations and in the provision of advice and technical assistance to the awardee. Refer to the RFA for further information regarding SPECIAL REQUIREMENTS.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

The AHCPR requires applicants to include minorities and women in study populations. If women or minorities are excluded or inadequately represented in research, a clear and compelling rationale must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 15, 1994, a letter of intent that includes the name, address, and telephone number of the Principal Investigator; identifies co-investigators and other key personnel and member institutions, community-based organizations, and any other participating organizations or institutions; and states the number and title of the RFA in response to which the application may be submitted. A letter of intent is not required, is not binding, and does not enter into the consideration of any subsequent applications. The letter of intent is to be sent to Dr. Norman W. Weissman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The RFA contains important information for applicants, including special application procedures; see INQUIRIES. The application receipt date is May 17, 1994. The application should be submitted on form PHS 398 (rev. 9/91) available from most institutional offices of sponsored research and the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Conference for Prospective Applicants

The AHCPR plans to convene a conference for prospective applicants in Kansas City, Missouri on March 28, 1994. Attendance is not a prerequisite to applying. Attendees must pay for their own travel and accommodation costs. For information contact Ms. Jean Carmody at telephone (301) 594-1357, extension 130, FAX (301) 594-2155.

REVIEW CONSIDERATIONS

Applications will be reviewed initially by the Division of Research Grants, NIH, for completeness and by AHCPR staff for responsiveness to the RFA. Incomplete and/or non-responsive applications will be returned to applicants without further consideration. Applications will be evaluated in accordance with the criteria stated in the RFA for scientific/technical merit by an appropriate peer review group. Review considerations and special review criteria are listed in the RFA.

INQUIRIES

For a copy of the RFA, call (301) 594-1357, extension 134.

Direct inquiries regarding programmatic issues to:

Norman W. Weissman, Ph.D., Director
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 502
Rockville, MD 20852-4908
Telephone: (301) 594-1357, extension 130.

Direct inquiries regarding fiscal matters to:

Ralph L. Sloat, Grants Management Officer
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852-4908
Telephone: (301) 594-1447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance number 93.226. Awards are made under authorization of the Public Health Service Act, Title IX, and administered under the PHS Grants Policy Statement and Federal Regulations 42 CFR 67, Subpart A. This program is not subject to the intergovernmental review requirements of Executive Order 12372.

OCCUPATIONAL RADIATION AND ENERGY-RELATED HEALTH RESEARCH

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFA AVAILABLE: OH-94-001

P.T. 34; K.W. 0725015

National Institute for Occupational Safety and Health

Letter of Intent Receipt Date: April 1, 1994

Application Receipt Date: May 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) is soliciting grant applications for research projects relating to occupational safety and health concerns associated with occupational exposures to radiation and other hazardous agents at Department of Energy (DOE) facilities and in other energy-related industries. Studies in the nuclear power industry and deliberate exposure of human subjects in radiation experiments are outside the scope of this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This RFA, Occupational Radiation and Energy-Related Health Research, is related to the priority area of occupational safety and health. A copy of "Healthy People 2000" (Full Report: Stock No 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone (202) 783-3238).

ELIGIBLE APPLICANTS

Eligible applicants include domestic and foreign non-profit and for-profit organizations, universities, colleges, research institutions, and other public and private organizations, including State and local governments and small, minority and/or woman-owned businesses.

MECHANISMS OF SUPPORT

Research support may be obtained through applications for a regular research grant (R01). Applicants for R01s may request support for up to three years. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also.

FUNDS AVAILABLE

For fiscal year (FY) 1994, approximately \$500,000 is available to fund projects ranging in amount from \$25,000 to \$200,000 in total costs.

RESEARCH OBJECTIVES

Background

The Secretary, Department of Health and Human Services (HHS) and the Secretary, Department of Energy (DOE) signed a Memorandum of Understanding (MOU) transferring the authority and resources to manage and conduct energy-related analytic epidemiologic research from DOE to HHS. This includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DOE facilities; other workers potentially exposed to radiation; and workers exposed to potential hazards resulting from non-nuclear energy production and use.

Scope

The focus of grants should reflect: (1) retrospective occupational exposure assessment, (2) radiation measurement issues, (3) non-cancer morbidity and mortality outcomes, (4) meta-analysis and combined analysis methodologies, (5) uncertainty analysis, and (6) effects of measurement error on risk estimates.

STUDY POPULATIONS

Applicants are required to give added attention (where feasible and appropriate) to the inclusion of minorities and/or women study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. Exceptions would be studies of diseases that exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. If minorities and/or women are not included in a given study, a clear rationale for their exclusion must be provided.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 1, 1994, a letter of intent that includes a descriptive title of the proposed effort, the name and address of the principal investigator, the names of other key personnel, and the participating institutions, and the number and title of this RFA. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. This letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application.

The letter of intent is to be sent to Dr. Fleming at the address listed under INQUIRIES.

APPLICATIONS PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from NIOSH program administrator listed under INQUIRIES.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number, Radiation Studies, OH-94-001, must be typed on line 2a of the face page of the application form and the YES box must be marked." Applications submitted in response to this RFA must be received on May 18, 1994.

Submit a signed, typewritten original of the application, including the Checklist, and five photocopies of the PHS 398, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The timetable for receiving applications and awarding grants in fiscal year 1994 is:

| | |
|--------------------------------|--------------------|
| Letter of Intent Receipt Date: | April 1, 1994 |
| Application Receipt Date: | May 18, 1994 |
| Initial Review: | August 1994 |
| Secondary Review: | September 1994 |
| Earliest Possible Start Date: | September 30, 1994 |

Applications must be received on the above receipt date. To guard against problems caused by carrier delays, retain a legible proof-of-mailing receipt from the carrier, dated no later than one week prior to the receipt date. If the receipt date falls on a holiday, it will be extended to the following work day.

REVIEW CONSIDERATIONS

Applications will be reviewed by an initial review group convened by the NIOSH. The initial (peer) review is based on scientific merit and significance of the project, competence of the proposed staff in relation to the type of research involved, feasibility of the project, likelihood of its producing meaningful results, appropriateness of the proposed project period, adequacy of the applicant's resources available for the project, and appropriateness of the budget request.

AWARD CRITERIA

In the secondary (programmatic importance) review, the following factors will be considered:

- o The results of the initial review;
- o Magnitude of the problem in terms of numbers of workers affected;
- o Severity of the disease or injury in the worker population; and
- o Usefulness to applied technical knowledge in the identification, evaluation, and/or control of occupational safety and health hazards.

Applicants will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Roy M. Fleming, Sc.D.
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Building 1, Room 3053, Mail Stop D-30
Atlanta, GA 30333
Telephone: (404) 639-3343

Direct inquiries regarding fiscal matters to:

Ms. Lisa Tamaroff
Grants Management Branch, PGO
Centers for Disease Control and Prevention
255 E. Paces Ferry Road, NE
Room 300, Mail Stop E-13
Atlanta, GA 30305
Telephone: (404) 842-6796

AUTHORITY AND REGULATIONS

This program is authorized under the Public Health Service Act, as amended, Section 301 (42 U.S.C. 241); the Occupational Safety and Health Act of 1970, Section 20 (a) (29 U.S.C. 669[a]); and the Federal Mine Safety and Health Amendments Act of 1977, as amended, Section 501 (30 U.S.C. 951). The applicable program regulations are in 42 CFR Part 52. The Catalog of Federal Domestic Assistance number is 93.262. This program is not subject to the Public Health System Reporting Requirements. Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

CARDIOVASCULAR CONSEQUENCES OF SLEEP APNEA

NIH GUIDE, Volume 23, Number 7, February 18, 1994

RFA AVAILABLE: HL-94-009

P.T. 34; K.W. 0715040, 0715187, 0785035

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: April 1, 1994
Application Receipt Date: May 23, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Lung Diseases, Division of Epidemiology and Clinical Applications, and the National Center on Sleep Disorders Research are undertaking the development of a collaborative clinical study of cardiovascular consequences of sleep apnea, to be conducted in well characterized, existing population-based cohorts. Goals include determining the degree to which sleep apnea and milder degrees of sleep-related breathing disorders (SRBD) are independent or contributing risk factors for the development of cardiovascular and cerebrovascular disease, as well as examining possible associations with other cardiovascular risk factors. This RFA is both for clinical centers and the data coordinating center. It is estimated that the study will involve five to six clinical centers, each recruiting approximately 900 to 1,000 participants for in-depth studies of sleep apnea and SRBD from existing epidemiological cohorts. The solicitation is for five years.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cardiovascular Consequences of Sleep Apnea, is related to the priority areas of heart disease and stroke, clinical prevention services, diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit, and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply and any international component of a domestic application must be minor in its magnitude and critical in what it would contribute. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to undertake this program will be a cooperative agreement (U01), an assistance mechanism. Under the cooperative agreement, the NIH assists, supports, and/or stimulates and is substantially involved with recipients in conducting a study by facilitating performance of the effort in a "partner" role. The anticipated award date is September 30, 1994.

FUNDS AVAILABLE

An estimated five to six awards for Clinical Centers and one award for a Data Coordinating Center will be made under this RFA. A maximum of about \$16.3 million (including direct and indirect costs) over a five-year period will be awarded for the Clinical Centers and the Data Coordinating Center. Approximately \$3.0 million will be available for the first year, \$3.1 million for the second year, \$3.3 million for the third year, \$3.4 million the fourth year and \$3.5 million for the last year. It is anticipated that the award for each Clinical Center will be about \$400,000 total costs for the first year and the award for the Data Coordinating Center will be about \$600,000 total costs for the first year.

Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will also vary in all years.

At this time, the NHLBI anticipates that there may be a renewed competition after five years. However, the final decision will depend upon experience with the program during the first five years as well as financial considerations.

RESEARCH OBJECTIVES

Snoring, the most common symptom of sleep disordered breathing, has been implicated as a risk factor for the development of hypertension, ischemic heart disease, and cerebral infarction. Many of the adverse cardiovascular effects of snoring have been attributed to the substantial prevalence of obstructive sleep apnea among habitual snorers.

The profound physiological derangements (hypoxemia, severe hypertension, tachycardia, fragmentation of sleep, arrhythmias) that often occur in association with sleep disordered breathing provide biologically plausible explanations for associations between sleep apnea and cardiovascular morbidity. However, it is not known whether sleep apnea is an independent vascular disease risk factor or a concomitant of established vascular or cerebral diseases or other risk factors (such as obesity or hypertension). Similarly, little is known regarding potential interactions between sleep apnea and other risk factors, or whether specific population subgroups may be particularly susceptible to adverse cardiovascular and cerebrovascular consequences associated with sleep apnea. Identification of factors that predispose to increased risk for SRBD is important for public health policy and for developing an improved understanding of disease pathogenesis that may include interactions among a number of risk factors in causing morbidity. This program seeks to accomplish this with an interactive, coordinated group of clinical centers working under a common protocol.

This program is to be built upon established epidemiologic programs. It is anticipated that the sleep study would make use of data previously collected in existing cohort studies as well as any outcome information. For example, a number of studies supported by NHLBI, other components of NIH, National Center for Health Statistics, and other agencies have already collected much of the baseline information on hypertension, obesity, and other cardiovascular risk factors as well cardiovascular outcomes needed to examine relationships with sleep apnea and SRBD. Several epidemiology studies also include questionnaires on snoring that could be used to identify persons at high risk of sleep apnea.

A total population of approximately 6,000 participants is anticipated. The sleep study population may include a wide range of samples from 40 years of age and above. It is not essential that all Clinical Centers have access to the full age range of subjects since certain established cohorts may be particularly suited to provide a unique aspect (age, gender, race, etc.) of their population for this program.

The overall population to be studied should provide data that are broadly applicable to diverse minority groups as well as whites; thus, the composition of the study population in this RFA program must reflect this diversity.

The timetable for this program may be roughly subdivided into three phases over a five year period. Phase I consists of planning and protocol development; phase II subject recruitment, protocol implementation, examinations and follow-up; phase III data analysis and prepare reports.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, the NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. C. James Scheirer at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; or from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NHLBI program staff listed under INQUIRIES. Applications must be received by May 23, 1994. If an application is received after this date it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Applicants are encouraged to submit and describe their own ideas on how best to meet the goals of the study, but they are expected to address issues identified under SPECIAL REQUIREMENTS of the RFA. Note that this document is not the RFA. Applications will be judged primarily on the scientific quality of the application, the appropriateness, facilities and access to subjects from existing, established epidemiology studies, adequacy of existing data, multidisciplinary nature of the study and group, approach to cost containment, the discussion of considerations relevant to this RFA, expertise of the investigators, their capability to perform the work proposed, and a demonstrated willingness to work as part of the collaborative group and with the NHLBI Project Scientist.

The review group will assess (as further detailed in the RFA):

Clinical Centers

- o Ability to utilize existing, established epidemiological cohorts to address the goals of this program; adequacy of the population and data set, and access to recruit the required numbers of subjects, including appropriate representation of minorities and women.
- o Scientific merit of the proposed sleep study protocol.
- o Qualifications, experience, and commitment of key personnel, including their previous experience conducting clinical or population based research.
- o Facilities, equipment and organizational structure to implement the protocol.
- o Rationale and cost-effectiveness of the research approach proposed.

Data Coordinating Center

- o Scientific merit of the proposed research protocol.
- o Organizational, administrative, and supervisory ability and statistical expertise to serve as a Data Coordinating Center for multicenter, clinical or population based research.
- o Qualifications, experience, and commitment of key personnel.
- o Facilities, equipment and sub-contracts to function as a Data Coordinating Center.
- o Appropriateness of the budget for the work proposed.

AWARD CRITERIA

Applications recommended by the National Heart, Lung, and Blood Advisory Council will be considered for award based upon: (a) scientific and technical merit; (b) program balance, including in this instance, sufficient compatibility of features to make a successful collaborative program a reasonable likelihood; and (c) availability of funds.

Letter of Intent Receipt Date: April 1, 1994
Application Receipt Date: May 23, 1994
Review by NHLBI Advisory Council: September 1-2, 1994
Anticipated Award Date: September 30, 1994

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Inquiries regarding this RFA and requests for the RFA may be directed to:

James P. Kiley, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A15
Bethesda, MD 20892
Telephone: (301) 594-7443
FAX: (301) 594-7487

Direct inquiries regarding review and application procedures and address the letter of intent to:

C. James Scheirer, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 648
Bethesda, MD 20892
Telephone: (301) 594-7452
FAX: (301) 594-7407

Inquiries regarding fiscal and administrative matters may be directed to:

Mr. Raymond L. Zimmerman
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11C
Bethesda, MD 20892
Telephone: (301) 594-7420
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This project is described in the Catalog of Federal Domestic Assistance No. 93.837. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR 74. This project is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MARC FACULTY RESEARCH FELLOWSHIPS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PAR NUMBER: PAR-94-032

P.T.

National Institute of General Medical Sciences

Application Receipt Dates: April 5 and December 5

THIS IS A RE-PUBLICATION OF THE PROGRAM ANNOUNCEMENT THAT APPEARED IN THE NIH GUIDE FOR GRANTS AND CONTRACTS ON FEBRUARY 4, 1994. PLEASE DISREGARD THE PREVIOUS VERSION.

PURPOSE

The Minority Access to Research Careers (MARC) Program of the National Institute of General Medical Sciences (NIGMS) provides research training opportunities for faculty and students at four-year colleges that have a substantial enrollment of students from underrepresented minority groups. As part of its ongoing commitment towards enhancing the research and research training environment at these colleges, NIGMS provides support for faculty at these institutions to enhance their research skills. This announcement describes the newly revised MARC Faculty Fellowship Programs. Faculty members who are recent recipients of the doctoral degree are encouraged to apply for the regular Postdoctoral Fellowship Award (F32) or to seek support at institutions with Institutional Postdoctoral Training Grants; there is no special MARC postdoctoral training program for these individuals. Information about F32 fellowships and training grants may be obtained from the relevant NIH Institute.

MARC Faculty Predoctoral Fellowship

The purpose of this program is to strengthen the research and research training opportunities of minority institutions by providing an opportunity for eligible faculty who lack the Ph.D. degree (or equivalent) to obtain the research doctorate. The expectation is that the candidate's training in a setting away from the home institution will expose the candidate to new ideas and will enhance the research and teaching environment of the home institution when the candidate returns.

MARC Faculty Senior Fellowship

The purpose of this program is to allow eligible faculty of minority institutions the opportunity to update their research skills and/or move into new areas of research through a year-long period of intensive research in a state-of-the-art research environment. The faculty member would have only minimal responsibilities at the home institution during the training period. The expectation is that these new skills will enhance the research and teaching environment of the home institution.

ELIGIBILITY REQUIREMENTS

MARC Faculty predoctoral and senior fellowships have the following common requirements. In addition, each mechanism has a few of its own specific requirements.

To be eligible for either type of fellowship a candidate must:

- o be full-time, permanent faculty in biomedically-related science or mathematics at the home institution for at least three years at the time of submission of the application; (Note, permanent does not mean tenured or tenure-track but implies the expectation of continued employment in the normal course of events. Adjunct or part-time faculty are not eligible.)
- o intend to return to the home institution at the end of the training period;
- o demonstrate a commitment to research and teaching in a minority institution;
- o be seeking training in a science (including mathematics) related to biomedical or behavioral research; AND
- o be a citizen or a non-citizen national of the U.S., or have been lawfully admitted for permanent residence in the U.S., at the time of application.

In addition, at the time of application for a MARC Faculty Predoctoral Fellowship, the candidate must be enrolled in OR have been accepted by and agreed to enroll in a Ph.D. or combined M.D./Ph.D. (or other combined professional doctorate/Ph.D.) training program in the biomedical or behavioral sciences.

In addition, at the time of application for a MARC Faculty Senior Fellowship, at least seven years must have elapsed since the candidate received the Ph.D. degree or equivalent research or professional doctorate.

The home institution is the college or university where the candidate is employed at the time of the application. The home institution must:

- o be a domestic private or public minority institution, that is, one with a significant enrollment of underrepresented minorities. For purposes of this announcement, underrepresented minorities are individuals belonging to racial/ethnic groups underrepresented in the biomedical or behavioral sciences. Nationally, these groups include African Americans, Hispanic Americans, Native Americans, and Pacific Islanders. Institutions must document eligibility by providing appropriate enrollment data;

- o offer at least the baccalaureate degree in the biomedical or behavioral sciences or mathematics;
- o support the candidate's plans for training; AND
- o guarantee and provide appropriate release time for faculty for research training.

The training institution is the research university or research institution/center at which the training takes place. It may be a public or private, domestic or foreign institution. The training institution:

- o must offer a solid research environment as evidenced by a high-level of faculty involvement in biomedical research and a high-level of research support through competitive grants (or similar quality-based support, such as Howard Hughes Medical Institute support);
- o may NOT be the candidate's home institution; and
- o will be the sponsoring (applicant) institution.

In addition, the sponsor, who will direct the candidate's research, must be a faculty member (or equivalent) at the training institution and have a distinguished record of achievement in research documented by high quality research publications and/or competitive research grant support.

MECHANISM OF SUPPORT

Awards under the MARC Faculty Predoctoral Fellowship will use the faculty fellowship (F34) award. Applicants may request up to five years of support. An applicant may request ONLY the following: a stipend equal to the actual annual salary, but not to exceed the stipend of a level 1 postdoctoral fellow (currently \$20,700); tuition and fees as determined by the training institution; and an institutional allowance of \$2000 per year to be used for costs directly related to the candidate's training. Funds will not be provided for purchasing equipment, although the institutional allowance may be used for this purpose PROVIDED that the equipment is DIRECTLY related to the candidate's training. No indirect costs will be paid. The candidate's stipend may be supplemented by either the home institution or the training institution using funds from non-Federal sources only.

Awards under the MARC Faculty Senior Fellowship will use the senior fellowship (F33) award. Note that even though this mechanism is widely used throughout the NIH, applicants for the MARC Faculty Senior Fellowship should be aware of different eligibility requirements and review criteria. Applicants may request no less than one academic year (9 months) and no more than two years of support.

A MARC Faculty Senior Fellowship applicant may request a stipend equal to the actual annual salary, but not to exceed the stipend of a level 7 postdoctoral fellow (currently \$32,300); the actual amount of the stipend awarded will be prorated by the length of the award if the award is for less than 12 months. An applicant may also request an institutional allowance of \$3000 per year to be used for expenses directly related to the candidate's training. No funds will be provided for purchasing equipment, travel, or housing. However, the institutional allowance may be used for equipment or travel to a scientific meeting provided that these are DIRECTLY related to the candidate's training. No indirect costs will be paid. The candidate's stipend may be supplemented by either the home institution or the training institution using non-Federal sources of funds only.

MARC Faculty Senior Fellows will incur a payback obligation during the first 12 months of training, which can be satisfied on a month-by-month basis either by additional research training or by resuming a career in research or teaching. See the NIH Guide for Grants and Contracts, Vol. 22, No. 27, July 30, 1993, for more details.

TRAINING OBJECTIVES

The purpose of the MARC Faculty Fellowship Program is to enhance the research and research training capabilities of the home institution by offering faculty the opportunity to obtain training for the research doctorate OR, for those faculty with doctorates, to update or enhance their research skills through high quality research experiences. The expectation is that this training will enable the faculty to be better researchers, mentors, trainers, and role models in the home institution.

APPLICATION PROCEDURES

Applicants for MARC Faculty Predoctoral or MARC Faculty Senior Fellowships must use the Individual National Research Service Award form PHS 416-1 (rev. 10/91). These forms are available in most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, NIH, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIGMS MARC Program Office, at the address listed under INQUIRIES.

If, at the time of application for a MARC Faculty Predoctoral Fellowship, the candidate has selected a research thesis advisor, that individual should serve as the sponsor. If a candidate has not yet selected a research thesis advisor, the head of the graduate program should nominate someone to serve as the candidate's sponsor. The application should indicate clearly that this is an interim arrangement and should describe procedures for selecting a permanent research thesis advisor.

An application for either MARC Faculty Fellowship must contain a letter signed by appropriate officials of the HOME INSTITUTION, including the candidate's department head, (1) supporting the candidate's training plans; (2) guaranteeing the necessary release time for the candidate; (3) certifying the candidate's eligibility for the program; and (4) establishing the institution's eligibility as a minority institution through enrollment data. In addition, for MARC Faculty Predoctoral Fellowship candidates, this letter must describe the institution's commitment to the candidate.

Submit a signed, typewritten original of the application, including the Checklist, at least three reference letters, the letter of support from the home institution, and two photocopies of the signed application in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications will be accepted for the April 5 and December 5 fellowship receipt dates ONLY. They will not be accepted for the August receipt date.

In item 3, applicants must give the Program Announcement number, PAR-94-032. In item 2, the name of the appropriate MARC Faculty Fellowship Program, Predoctoral or Senior, must be typed.

REVIEW CONSIDERATIONS

Applications will be evaluated for completeness by the Division of Research Grants and eligibility by staff in the NIGMS before review. Only those found to be complete and eligible will be reviewed for technical merit; others will be returned without review.

Applications will be evaluated in accordance with the criteria stated below for scientific, technical, and training merit by appropriate peer review groups. NIGMS review committees will review the MARC Faculty Predoctoral Fellowship applications and committees from the Division of Research Grants will review the MARC Faculty Senior Fellowship applications. The second level of review for both types of fellowships will be provided by the senior staff in the NIGMS. It is critical that each application contain sufficient information about each element to enable the reviewers to make a reasoned evaluation.

Review criteria

- o the applicant's qualifications and potential for a career as a researcher and teacher:

for MARC Faculty Predoctoral Fellowship candidates, assessment will include academic record, honors, research experience, scientific publications and/or presentations, references, and training and career goals;

for MARC Faculty Senior Fellowship candidates, assessment will include research and teaching experience, professional honors and awards, scientific publications and/or presentations, training and career goals, references, and plans for using research training to enhance research and teaching at the home institution;

- o quality and appropriateness of the proposed research training, including the specific research proposal; and

- o quality of the training environment, including, but not limited to, the qualifications and grant support of the sponsor.

AWARD CRITERIA

Awards will be made on the basis of the technical merit of the application. Among highly qualified candidates, preference may be given to those who demonstrate a strong commitment to research and teaching at a minority institution and who present evidence of strong support from the home and the training institutions, including the research sponsor.

Review Schedule

| | | |
|----------------------------|-----------|------------|
| Application Receipt Dates: | April 5 | December 5 |
| Initial Review: | June | February |
| Secondary Review: | August | April |
| Earliest Start: | September | May |

INQUIRIES

Inquiries about the MARC Faculty Fellowship Programs are welcome. Questions concerning programmatic issues, including institutional eligibility, may be addressed to:

Dr. Yvonne Maddox
Minority Access to Research Careers Program
National Institute of General Medical Sciences
Westwood Building, Room 950
Bethesda, MD 20892
Telephone: (301) 594-7823

Questions concerning fiscal matters may be addressed to

Ms. Toni Holland
National Institute of General Medical Sciences
Westwood Building, Room 935
Bethesda, MD 20892
Telephone: (301) 594-7819

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.880, Minority Access to Research Careers. Awards are authorized by sections 301 and 405 of the Public Health Service Act, as amended and administered under PHS grants policies and federal Regulations 45 CFR Part 74 and 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health systems Agency review.

MORE FACULTY DEVELOPMENT AWARD

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PAR NUMBER: PAR-94-034

P.T.

National Institute of General Medical Sciences

Application Receipt Dates: February 1, June 1, and October 1

PURPOSE

The Minority Access to Research Careers (MARC) Program of the National Institute of General Medical Sciences (NIGMS) provides research training opportunities for faculty and students at four-year colleges that have a substantial enrollment of students from underrepresented minority groups. As part of its ongoing commitment towards enhancing the research and research training environment at these colleges, NIGMS provides support for faculty at these institutions to enhance their research skills. This announcement describes the new Faculty Development Award from the NIGMS Minority Opportunities for Research (MORE) Branch. This new program provides support for eligible faculty to spend the summer (or one academic term) every year for two to five years in full-time research in a research-intensive laboratory.

ELIGIBILITY

A candidate must:

- o be full-time, permanent faculty in biomedically-related science or mathematics at the home institution for at least three years at the time of submission of the application; (Note, permanent does not mean tenured or tenure-track but implies the expectation of continued employment in the normal course of events. Adjunct or part-time faculty are not eligible.);
- o have received the Ph.D. or equivalent at least seven years before the date of the application;
- o intend to return to the home institution at the end of the training period;
- o demonstrate a commitment to research and teaching in a minority institution;
- o plan to conduct research in a science (including mathematics) related to biomedical or behavioral research; AND
- o be a citizen or a non-citizen national of the U.S., or have been lawfully admitted for permanent residence in the U.S., at the time of application.

The home institution is the college or university where the candidate is employed at the time of the application. The home institution must:

- o be a domestic private or public minority institution, that is, one with a significant enrollment of underrepresented minorities. For purposes of this announcement, underrepresented minorities are individuals belonging to racial/ethnic groups underrepresented in the biomedical or behavioral sciences. Nationally, these groups include African Americans, Hispanic Americans, Native Americans, and Pacific Islanders. Institutions must document eligibility by providing appropriate enrollment data;
- o offer at least the baccalaureate degree in the biomedical or behavioral sciences or mathematics;
- o support the candidate's plans; AND
- o guarantee and provide appropriate release time each year for the candidate for full-time research and to take courses at the research institution.

The research institution is the university or other institution at which the candidate conducts his/her full-time summer research and takes courses. It may be a public or private, domestic or foreign institution. The research institution:

- o must offer a solid research environment as evidenced by a high-level of faculty involvement in biomedical research and a high-level of research support through competitive grants (or similar quality-based support, such as Howard Hughes Medical Institute support); AND
- o may NOT be the candidate's home institution.

In addition, the sponsor, who will direct the candidate's research, must be a faculty member (or equivalent) at the research institution and should have a distinguished record of achievement in research documented by high quality research publications and/or competitive research grant support.

MECHANISM OF SUPPORT

Awards under this program will use the Minority School Faculty Development Award (K14). The applicant must request at least two years but not more than five consecutive years of support. The awards are renewable.

RESEARCH OBJECTIVES

The purpose of the MORE Faculty Research Award Program is to enhance the research and research training capabilities of the home institution by offering faculty the opportunity to update or enhance their research skills through high quality research experiences. The candidate will also have the opportunity to enroll in one course per academic term in fields directly related to the research in order to update his/her theoretical background. The expectation is that these new skills will enhance the research and teaching environment of the home institution. Ideally, the experience would lead to long-term collaborations between the candidate and the faculty of the research institution.

Additional Information

Candidates must engage in full-time research at the research institution for the summer (or other academic term) every year for at least two and not more than five consecutive years. Only ONE period of full-time research in a SINGLE academic OR calendar year will be supported. In addition, the candidate may enroll in one course per academic term at the research institution provided that the course is directly relevant to the candidate's research career development. All research and course work must be done at a single research institution unless an exception is granted by NIGMS in writing.

The application must contain a letter signed by appropriate officials of the HOME INSTITUTION, including the candidate's department head, (1) supporting the candidate's plans; (2) guaranteeing the necessary release time for the candidate; (3) certifying the candidate's eligibility for the program; and (4) establishing the institution's eligibility as a minority institution through enrollment data.

The application must also contain a statement, signed by the appropriate authorizing official, that the RESEARCH INSTITUTION agrees to the arrangements described in the application. If an award is made, the home institution and the research institution must establish the appropriate formal agreements.

The PROPOSED RESEARCH SPONSOR is considered to be "key personnel" for this project and should be listed on page 2 of the application. The application MUST include a biographical sketch (form page FF) and description of grant support (form page GG) for the proposed research sponsor. In addition, the application should contain a letter of commitment from the sponsor describing his/her support for the applicant's research plan.

Allowable Costs

An applicant may request a salary equal to the candidate's actual annual salary and appropriate fringe benefits prorated for the period of time during which the candidate is engaged in full-time research at the research institution; salary support will not be provided for the time the candidate is enrolled in an academic course. The applicant may also request up to \$3000 per year for supplies, equipment and other expenses, which may include travel to scientific meetings and/or the research site, provided that these costs are DIRECTLY related to the candidate's full-time research experiences. In addition, an applicant may request funds to pay tuition and fees for one course per academic term to be taken at the research institution. No funds will be provided for housing at the research site. Direct costs requested may not exceed \$50,000 in any year. Indirect costs will be provided at eight percent of allowable direct costs.

During the period of full-time research at the research institution, the candidate's salary may be supplemented by either the home institution or the research institution using non-Federal sources of funds only.

APPLICATION PROCEDURES

Applicants for the MORE Faculty Development Award (K14) are to use the regular research grant application form PHS 398 (rev. 9/91). These forms are available in many institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIGMS MARC Program Office at the address listed under INQUIRIES.

In Item 2a, the candidate must give the PA number (PAR-94-034) and type the title "MORE FACULTY DEVELOPMENT AWARD." In item 2b, the candidate should type "K14."

The HOME INSTITUTION will serve as the grantee institution.

Submit a signed, typewritten original of the application, including the Checklist and other required supporting material, and five photocopies of the signed application and any appendices in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications will be accepted for the following research application receipt dates: February 1, June 1, and October 1.

REVIEW CONSIDERATIONS

Applications will be evaluated for completeness by the Division of Research Grants and eligibility by staff in NIGMS before review. Only those found to be complete and eligible will be reviewed for technical merit; others will be returned without review.

Applications will be evaluated in accordance with the criteria stated below for scientific and technical merit by peer review groups in the Division of Research Grants. The second level of review will be provided by the senior staff in NIGMS. It is critical that the application contain sufficient information about each of these elements to enable the reviewers to make a reasoned evaluation.

Review criteria

- o the applicant's qualifications and potential for a successful career as a researcher and teacher at a minority institution assessed in terms of research and teaching experience; professional honors and awards; scientific publications and/or presentations; references; training and career goals; and plans for using research experiences to enhance the research and teaching capability of the home institution.
- o quality and appropriateness of the proposed research and, if applicable, the associated course work;
- o quality of the research environment at the research institution, including, but not limited to, the qualifications and grant support of the sponsor;

AWARD CRITERIA

Awards will be made on the basis of the technical merit of the application. In addition, among highly qualified candidates, preference may be given to those who demonstrate a strong commitment to research and teaching at a minority institution and who present evidence of strong support from the home and the research institutions, including the research sponsor.

Review Schedule

| | | | |
|----------------------------|-----------|----------|------------|
| Application Receipt Dates: | March 1 | July 1 | November 1 |
| Initial Review: | June | October | February |
| Secondary Review: | August | January | May |
| Earliest Start: | September | February | June |

INQUIRIES

Inquiries about the Faculty Development Award are welcome. Questions concerning programmatic issues, including institutional eligibility, may be addressed to:

Dr. Yvonne Maddox
Minority Access to Research Careers Program
National Institute of General Medical Sciences
Westwood Building, Room 950
Bethesda, MD 20892
Telephone: (301) 594-7823

Questions concerning fiscal matters may be addressed to

Ms. Toni Holland
Grants Management Specialist
National Institute of General Medical Sciences
Westwood Building, Room 935
Bethesda, MD 20892
Telephone: (301) 594-7819

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.880, Minority Access to Research Careers. Awards are authorized by sections 301 and 405 of the Public Health Service Act, as amended and administered under PHS grants policies and federal Regulations 45 CFR Part 74 and 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health systems Agency review.

NEUROGENETIC DISORDERS OF INFANCY AND CHILDHOOD

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PA NUMBER: PA-94-035

P.T. 34; K.W. 1002019, 1002030

National Institute of Neurological Disorders and Stroke

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) announces the reissuance of a program announcement (originally published July 18, 1985) to notify the scientific community of continuing NINDS interest in the submission of research grant applications concerning neurogenetic disorders.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, Neurogenetic Disorders of Infancy and Childhood, is related to the priority areas of chronic disabling conditions and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards, program projects (P01), and center grants (P50). Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

Applicants may use the research project grant (R01), program project (P01), center grants (P50), and FIRST (R29) award. Prospective applicants are encouraged to communicate with the NINDS program contact listed under INQUIRIES regarding the appropriate funding mechanism.

RESEARCH OBJECTIVES

Background

It is estimated that of the 3,000 known genetic disorders, as many as one-third are primarily neurologic or have important neurologic involvement. Most of them have a low incidence, but collectively they represent an enormous burden on affected individuals, their families, and society. Many of these neurogenetic disorders manifest themselves early in life leading to either a premature death or to a lifelong disability with significant attendant psychological and economic hardships.

Any attempt to group all the neurogenetic diseases of early life is somewhat arbitrary given that for many the underlying pathological mechanisms are incompletely understood. Examples of disorders of interest to the NINDS include:

1. Hereditary ataxias and related disorders such as Friedreich ataxia, ataxia telangiectasia, olivopontine cerebellar degeneration, Ramsay Hunt syndrome, abetalipoproteinemia, Machado-Joseph disease, and familial spastic paraparesis.
2. Movement disorders such as Juvenile Huntington disease, the dystonias including blepharospasm and spasmodic torticollis, tremor, myoclonus, and Hallervorden-Spatz disease.
3. Phakomatoses, or neurocutaneous syndromes such as neurofibromatosis, tuberous sclerosis, Sturge-Weber, and Von Hippel-Landau disease.
4. Mitochondrial encephalomyopathies such as the MELAS syndrome, Kearns-Sayre, and Leigh disease.
5. Hereditary disorders of nerve and muscle such as infantile spinal muscular atrophy, Charcot-Marie-Tooth disease, hereditary sensory and autonomic neuropathies, genetic myasthenic syndromes, metabolic myopathies, muscular dystrophies, and myotonias.

In addition to diseases that have their major effects on the nervous system, many inborn errors of metabolism affect several systems, including the nervous system. The NINDS is interested in supporting research in the metabolic diseases where the research proposed is directed at the nervous system manifestations of the disorder. Examples of these metabolic diseases include, but are not limited to:

1. Disorders of lipid metabolism such as Gaucher disease, Niemann-Pick disease, the neuronal ceroid lipofuscinoses including Batten disease, the leukodystrophies, and the gangliosidoses including Tay-Sachs disease.
2. Disorders of carbohydrate metabolism such as galactosemia and hereditary fructose intolerance.
3. Glycogen storage diseases such as Von Gierke, Lafora disease, and Pompe disease.
4. Organic acidurias such as propionic acidemia and methylmalonic acidemia.
5. Disorders of purine metabolism such as Lesch-Nyhan syndrome, and porphyria.
6. Disorders of amino acid metabolism and transport such as phenylketonuria, homocystinuria, maple syrup urine disease, urea cycle defects, Hartnup disease, and Lowe syndrome.
7. Disorders of mucopolysaccharide metabolism such as Hunter, Hurler, and Sanfilippo syndromes.
8. Disorders of metal metabolism such as Wilson disease and Menkes syndrome.

There are numerous other neurological disorders that also result from genetic abnormalities such as the Laurence-Moon-Bardet-Biedl, Aicardi, Sjogren-Larsson, Prader-Willi and Angelman syndromes. In addition to those diseases that have a recognizable pattern of inheritance, there are many other neurological disorders that seem to have, in some cases, a familial basis. These may well represent neurogenetic disorders with multifactorial etiology. Such diseases can be as diverse as disorders of defective cellular migration (such as lissencephaly, heterotopias), neural tube defects, congenital hydrocephalus, myoclonic epilepsy, and narcolepsy.

Research Goals and Scope

Grant applications to study human neurogenetic disorders involving affected individuals and their family members are encouraged. Because the phenotypes of many neurogenetic disorders do not appear until childhood or early adolescence, the development of animal models is also important. Such models could make possible the detection of early biochemical changes, allow characterizations of the chemical pathology, and facilitate study of how genetic mutation disrupts the normal pathways of nervous system function.

Areas of research interest include, but are not limited to, the following:

A. Clinical Pathologic Correlations. Studies are needed to delineate the relationship of the clinical picture to pathological findings. Histopathological studies, including neurochemical studies of fresh tissue, which provide data for basic understanding of the relationship between pathophysiology and the evolution of clinical signs and symptoms, as well as the course of the disorder are encouraged.

B. Genetics. Classical genetic studies have been used to establish the mode of inheritance for many of these disorders. This information will provide insight as to whether etiologic heterogeneity exists, and if sporadic cases are due to reduced penetrance or represent phenocopies. The most important contributions of genetic studies would be to establish the linkage relationships of the genes responsible for these disorders, and the identification of the defective gene and its normal biological role. State of the art methodologies for such studies should be used.

C. Biochemistry. Studies should be directed at discovering the metabolic defect in each of these disorders and identifying its molecular basis. Successful biochemical studies will lead to an understanding of the pathogenic mechanisms and make possible the recognition of the heterozygote. Currently available advanced and sophisticated methodologies should be brought to bear on this important research.

D. Neuroimaging. New neuroimaging technologies (PET, SPECT, MRI) can be applied to neurogenetic research problems and provide important clues about brain function under pathophysiological conditions and allow for correlation with the clinical disease state.

E. Neuroepidemiology. There are some neurological diseases in which the genetic abnormality may not be the primary reason for the expression of the disorder. Epidemiological study of at risk families or clusters of cases might provide important clues of the interaction between genetic and non-genetic factors in producing the clinical symptomatology.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group. In addition, gender and racial or ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups; however, the NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial or ethnic minority populations: Native Americans (including American Indians or Alaska Natives), Asian or Pacific Islanders, Blacks, and Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and prevention strategies), diagnosis, or treatment of diseases, disorders, or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded; however, every effort should be made to include human tissues from women and racial or ethnic minorities when it is important to apply the results of the study broadly. This directive should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully. Since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' population, including minorities.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to the NIH are required to address these policies. If the required information is not contained within the application, the review will be deferred until the information is provided. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) according to the instructions included in the application package. These application packages are available at the offices of sponsored research of most institutions eligible to receive Federal grants and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7249.

Applicants for program project grants should request a copy of the NINDS Guidelines: Program Project and Research Center Grants from the program staff listed under INQUIRIES. Receipt dates for new research project grant (R01) applications and FIRST (R29) awards and for program project (P01) and center grant (P50) applications are February 1, June 1, and October 1.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

On page 1 of form PHS 398, check "YES" in Item 2a, enter the number of this Program Announcement in the space provided, and provide the name of this Program Announcement (Neurogenetic Disorders of Infancy and Childhood) in the blank space labeled "Title."

Use the mailing label provided in the application package to mail the signed original and five exact copies of it to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

For program projects or center grants, submit the original and three copies to the Division of Research Grants. An additional two copies of the program project or center grant application must be sent to Dr. Judy Small at the address listed under INQUIRIES to expedite the processing of these applications for multidisciplinary efforts.

REVIEW CONSIDERATIONS

Several other Institutes at the National Institutes of Health also have an interest in supporting areas of research covered by this PA. Applications will be assigned on the basis of established Public Health Service referral guidelines and some applications may receive dual assignments. In the case of R01 and R29 applications, they will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard

NIH peer review procedures and criteria. Program project applications will be reviewed by initial review groups organized by the Institute to which the application is assigned. Following scientific-technical review, the applications will receive a second-level review by the Institute's national advisory council.

AWARD CRITERIA

The standard review criteria will be used to assess the scientific merit of applications. Applications will compete for available funds with all other applications. The following will be considered when making funding decisions:

- o quality of the proposed projects as determined by peer review,
- o availability of funds, and
- o program balance among research areas.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Questions concerning scientific aspects of this Program Announcement and application procedures may be addressed to:

Dr. Judy A. Small
Division of Convulsive, Developmental, and Neuromuscular Disorders
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C04
Bethesda, MD 20892
Telephone: (301) 496-5821
FAX: (301) 402-0887

Questions concerning fiscal aspects of this Program Announcement may be addressed to:

Mr. King P. Bond, Jr.
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

This program is described in the Catalogue of Federal Domestic Assistance, Number 93.853, Clinical Research Related to Neurological Disorders, and 93.854, Biological Basis Research in the Neurosciences. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR 74. This program is not subject to Health Services Agency review of the intergovernmental review requirements of Executive Order 12372.

CHARACTERIZATION AND TREATMENT OF GENETIC METABOLIC DISEASES

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PA NUMBER: PA-94-036

P.T. 34; K.W. 0715135, 1002019, 0765035, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases

PURPOSE

The purpose of this program announcement is to encourage research grant applications studying the mechanisms underlying the pathophysiology of genetic metabolic diseases. Research should be aimed at elucidating the genetic defects, examining their metabolic consequences, and devising and testing possible therapies for this group of devastating diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Characterization and Treatment of Genetic Metabolic Diseases, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards and program projects (P01). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the NIH research project grant (R01), FIRST (R29) awards, and program projects (P01). All investigators interested in submitting a program project will need to discuss the application with NIDDK staff and obtain the NIDDK Program Project Guidelines prior to applying for support via this mechanism. The use of Interactive Research Project Grants (IRPG) is encouraged for multi-disciplinary approaches to this complex problem. Further information on the IRPG mechanism is available in the NIH Guide, Vol. 22, No. 16, April 23, 1993.

RESEARCH OBJECTIVES

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports research on identifying and understanding the basic defects in causing genetic metabolic diseases, identifying alternative metabolic pathways, characterizing toxic metabolites and the mechanisms of their effects on multiple organs, development of animal models for these disorders, and treatment of these disorders including enzyme replacement therapy, dietary therapy, drug therapy and gene therapy. The diseases of interest include disorders of cellular transport, lysosome metabolism, peroxisome metabolism, amino acid and organic acid metabolism, carbohydrate metabolism, purine and pyrimidine metabolism, metal metabolism, lipid metabolism, and mucopolysaccharide metabolism.

Background

The NIDDK has a continuing interest in supporting research in the area of genetic metabolic diseases. The Metabolic Diseases and Gene Therapy Research Program has a large portfolio of regular research and program project grants that study genetic metabolic diseases. For many of these diseases, the enzyme defects have been identified and the genes that are mutated have been cloned with grant support from this program. In addition, the NIDDK has recently funded three core centers for gene therapy of cystic fibrosis and other genetic diseases to accelerate progress in the development of this important technology.

The diseases that historically have made up Garrod's inborn errors of metabolism are due to defects in particular enzymes that result in the use of alternative metabolic pathways, the production of abnormal metabolites and frequently the aberrant storage of undigested materials. In many cases, it is the build up of these aberrant metabolites that is toxic to several organ systems. With extension of the lifespan of patients with these diseases through therapy, it has become increasingly evident that most metabolic diseases affect several organ systems. One such example is Galactosemia. When this life-threatening liver disease is prevented by dietary restrictions, additional manifestations develop in other organs such as the ovarian failure, which is unmasked by treatment. Although treatment of primary manifestations is an important approach with tremendous therapeutic value, to adequately address the multisystemic nature of these disorders it is important to develop methods to correct the basic defect systemically.

Scope

Some examples of research topics that would be considered responsive to this solicitation include, but are not limited to, the following:

- o Identification of Basic Defects: This would include identifying the protein or enzyme that is defective, isolating the gene that is abnormal, identifying the mutations that cause the syndrome, and studying the structural and functional properties of both the normal and defective protein including X-ray crystallographic studies. Another important area is the development or improvement of diagnostic testing to enable earlier prenatal detection of metabolic diseases.

- o Cellular and Animal Models of the Metabolic Diseases: Cellular and animal models are particularly important for studying the underlying metabolic disturbance and for testing potential therapies. Cellular models would include the culture of appropriate cell types that manifest the defect for further study. Animal models can include identification and characterization of naturally occurring mutations, the creation of a knock out mutant or the introduction of a point mutation by homologous recombination, and the development of a chemically induced model that mimics features of the disease.

- o Identification of Toxic Metabolites and their Mechanism of Action: Enzyme deficiencies generate abnormal and/or excessive metabolites that may then be shunted through alternative pathways for degradation. In many cases, these metabolites are harmful to a variety of organ systems. For many metabolic diseases whose symptoms are attributed to the production of toxic metabolites, the actual toxic metabolites have not been identified nor has the mechanism of their detrimental effects been fully elucidated. For example, recent findings that sphingosine, a sphingolipid breakdown product, inhibits the activity of protein kinase C in vitro could help explain the mechanisms of toxicity in the pathogenesis of the sphingolipidoses. This mechanism may result in a progressive dysfunction of the signal transduction pathway vital for cell viability. Research that focuses on such elements in order to explain the pathophysiology of genetic metabolic diseases is needed.

- o Identification of Genetic Modifiers: As the genotypes of many metabolic disorders are studied for their ability to predict severity of disease, it is clear that genes other than those causing the primary defect can modify the phenotype. One classic example is that the persistence of fetal hemoglobin gene expression modifies the beta-thalassemia phenotype and, as a result, these patients have a milder clinical course. Identification of genes that modify the phenotype of other common genetic mutations is needed to explain the etiology of multiple phenotypes within a single genotype.

- o Development of Enzyme Replacement Therapy: Enzyme replacement therapy has been attempted for several metabolic diseases; however, in most cases the enzyme is degraded prior to reaching the target tissue. Recently, two different protein modifications have led to the development of enzyme replacement therapy for ADA deficiency and Gaucher Disease. Research is needed to develop methods for producing large quantities of biologically active enzymes; modifications directing targeting into organelles such as peroxisomes and into specific tissues, for example, by ligand-mediated internalization through cell surface receptors; and increasing protein half-life by protein modification or genetic engineering of amino acids important for signaling protein degradation.

- o Development of Dietary or Drug Therapy: Current treatment for most metabolic diseases consists of dietary restrictions, vitamin supplementation and/or drug therapy to prevent the build up of toxic metabolites. Research into new or improved dietary or drug therapy based on an understanding of the metabolic defect is needed. One area of

research could be to develop drug therapy to prevent aggregation of mutant proteins and to promote proper folding and assembly of complex proteins.

o **Development of Gene Therapy:** The area of gene therapy for metabolic diseases has evolved quickly. In order to further accelerate progress, many new directions must be evaluated for their feasibility as approaches for gene therapy. Studies of new viral vectors, chimeric vectors, improved techniques for homologous recombination and improvement in delivery vehicles such as liposomes and receptor-mediated endocytosis are examples of areas in need of further development.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Item 4 (Research Design and Methods) of the Research Plan AND summarized in Item 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, African Americans, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. basic research or clinical studies in which human tissue cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the regular application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institute of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or Principal Investigator should be included with the application.

For investigators applying for support through the FIRST award (R29), three letters of references must be submitted with the application. An applicant submitting a revised application in response to this RFA must again submit reference letters.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institute of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURES

Several other Institutes at the National Institutes of Health also have an interest in supporting areas of research covered by this PA. Applications will be assigned on the basis of established Public Health Service referral guidelines and some applications may receive dual assignments. In the case of R01 and R29 applications, they will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures and criteria. Program project applications will be reviewed by initial review groups organized by the Institute to which the application is assigned. Following scientific-technical review, the applications will receive a second-level review by the Institute's national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; and program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Requests for the NIDDK Program Project Guidelines and inquiries regarding programmatic issues may be directed to:

Dr. Catherine McKeon
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 594-7582
FAX: (301) 594-9011

Direct inquiries regarding fiscal matters to:

Ms. Donna Huggins
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
Bethesda, MD 20892
Telephone: (301) 594-7543

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.847. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

GENETIC DISORDERS CAUSING MENTAL RETARDATION

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PA NUMBER: PA-94-037

P.T.

National Institute of Child Health and Human Development

PURPOSE

The purpose of this Program Announcement (PA) is to encourage grant applications on genetic disorders that cause mental retardation. This includes research on molecular genetic mechanisms, biochemical and neuropathological processes in the brain, behavioral genetics, and other developmental processes that result in abnormal cognitive function. Research should be directed towards the screening, diagnosis, treatment, prevention, and/or amelioration of mental retardation and related developmental disabilities.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Genetic Disorders Causing Mental Retardation, is related to the priority area of chronic disabling conditions and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

Support of this program will be through the NIH research project grant (R01), FIRST (R29) award, and program project (P01) mechanisms. Investigators interested in submitting a program project are strongly encouraged to consult with NICHD program staff in the preparation of their applications. Applications of a multi-disciplinary nature may also be considered through the Interactive Research Project Grants (IRPG) program.

RESEARCH OBJECTIVES

Scope

About one-third of all genetic disorders show some neurological involvement, and many of these represent neurodegenerative diseases of infancy. Genetic or genetically-influenced conditions rank among the leading causes of organically-based mental retardation. These problems can be addressed through studies of the location, organization, and regulation of genetic material. This may include research on molecular genetic mechanisms (genomic imprinting, triplet repeats, mitochondrial inheritance), gene mapping, enzymatic function, behavioral genetics, prenatal diagnosis, genetic counseling, epidemiologic studies, animal models, and gene therapy.

Major areas of interest include:

- o Inborn errors of metabolism that specifically impact on brain function. This research focuses brain pathophysiology due to imbalances in amino acids, mucopolysaccharides, purines, lipids, and carbohydrates, or the dysfunction of cellular organelles (e.g., mitochondria, peroxisomes, lysosomes, or Golgi) that contributes to mental retardation and developmental disabilities. We are especially interested in the development of therapeutic strategies (genetic or pharmacological) that aid in the diagnosis and clinical management of these disorders. Specific examples of metabolic disorders with prominent MRDD include phenylketonuria, maternal phenylketonuria, Lesch-Nyhan, galactosemia, and adrenoleukodystrophy.
- o Down Syndrome is the leading genetic cause of mental retardation, occurring in about 1/800-1000 births. Research on Down Syndrome may focus on the behavioral heterogeneity, critical genes on chromosome 21, Alzheimer-like pathology, gene dosage compensation, chromosomal nondisjunction, cellular mosaicism, animal models, epidemiology, and prenatal screening issues.
- o Chromosomal abnormalities occur in three to four percent of live births. This may include aberrations associated with chromosome number, morphology, or structure. Partial deletions or duplications of chromosomal material are associated with contiguous gene syndromes (e.g., Charcot-Marie-Tooth, Smith-Magenis, Prader-Willi, Angelman, or WAGR), which often involve mental retardation. Chromosomal abnormalities may also affect placental development (confined placental mosaicism). Within the context of mental retardation, we are interested in molecular mechanisms that give rise to specific chromosomal abnormalities, genetic regulatory mechanisms (eg. genomic imprinting, uniparental disomy), epigenetic phenomena, and the identification of specific genes that affect brain function.
- o X-linked disorders may explain why males show a 25 to 35 percent higher incidence of mental retardation than females. We welcome research on genetic mechanisms specific to the X-chromosome (e.g., X-inactivation, gene regulation) that may be relevant to understanding some forms of X-linked mental retardation.
- o Fragile X syndrome is the leading cause of heritable mental retardation, affecting about 1/1400 males and 1/2500 females. The genetic defect is an unstable region of DNA on the X chromosome which becomes highly expanded when transmitted through the maternal lineage. Research on the expansion and transmission of triplet repeats, how they affect gene function, and the role of the FMR gene in brain function is encouraged. Support studies on the detection, behavioral assessment, and epidemiology of Fragile X syndrome in normal populations and in children with learning disabilities is also supported.
- o Rett syndrome is a neurological disorder that results in arrested development of motor and social skills at an early age, but it only appears in young girls (1/15,000 female births). The occurrence of this disorder suggests that it may involve spontaneous dominant mutations on the X chromosome, but more complex genetic models need to be considered. Research into the underlying defect in Rett Syndrome and how it affects brain development and behavior is especially encouraged.
- o Neural tube defects are among the most frequent and severe anomalies of central nervous system development, occurring in about 1/1000 live births. Although it appears that environmental as well as genetic factors play a role, the etiology and pathogenesis of these malformations are poorly understood. We support investigations in the genetic basis of neural tube defects, including the role of modifier genes that influence expression and penetrance, genetic networks (temporal and spatial) important for pattern formation in the developing brain and spinal cord, and animal models to elucidate mechanisms of normal neural tube development and to define the early developmental miscues that result in abnormal neural function.
- o Mitochondrial inheritance may explain some forms of mental retardation that cluster within families. Defects in oxidative phosphorylation and its by-products would be expected to impact most heavily on tissues like brain that have high energy demands and are sensitive to their metabolic environment. In order to understand the role of mitochondrial defects in mental retardation, we support research on mitochondrial genetics, regulation of mitochondrial function, replication, interaction of nuclear-encoded genes, and the development of model systems.
- o Development of animal models for specific brain disorders is rapidly advancing, thanks to advances in transgenic manipulation, stem cell culture, and embryology. We support the use of animal models for the study of pathophysiological mechanisms associated with brain dysfunction and the development of clinical strategies for the management of these disorders. We encourage research in behavioral genetics and comparative physiology in order to develop appropriate physiological and behavioral assessments.
- o Heterozygotes (carriers) often present phenotypic heterogeneity, which can complicate clinical management and counseling. In order to improve the assessment and treatment of mental retardation, we support research into the mechanisms of variable penetrance, allelic differences, genetic background, germ line mosaicism, X-inactivation, and/or

environmental differences in the expression of genetic disorders.

o Prenatal screening is central to the diagnosis and management of mental retardation and developmental disabilities. We support research in the development of safe and accurate methods for assessing the genetic status of the fetus, including amniocentesis, chorionic villus sampling, and analysis of fetal cells in the maternal circulation. We also support research in population genetics and the ethical, social, and legal consequences of these technologies.

o Gene therapy is being developed for the treatment of specific genetic disorders that affect brain function. We encourage research in those disorders in which mental retardation is the primary clinical manifestation. This may include development of improved vectors for brain tissue, transcriptional and translational control of inserted genes, physiological studies on the expression and function of gene products within the brain, transplantation of genetically-modified cells or tissues, and relevant animal models.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear and compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 (rev. 9/91) instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7249. The title and number of the announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Several other Institutes at the National Institutes of Health also have an interest in supporting areas of research covered by this PA. Applications will be assigned on the basis of established Public Health Service referral guidelines and some applications may receive dual assignments. In the case of R01 and R29 applications, they will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures and criteria. Program project applications will be reviewed by initial review groups organized by the Institute to which the application is assigned. Following scientific-technical review, the applications will receive a second-level review by the Institute's national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Ralph Nitkin
Mental Retardation and Developmental Disabilities Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 4809
Bethesda, MD 20892
Telephone: (301) 496-1383
FAX: (301) 402-2085

Direct inquiries regarding fiscal matters to:

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A-17
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

PREVENTIVE INTERVENTION RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PAR NUMBER: PAR-94-038

P.T. 34; K.W. 0745027, 0715129

National Institute of Mental Health

PURPOSE

The National Institute of Mental Health (NIMH) invites applications for Preventive Intervention Research Centers (PIRCs) whose main goal is to bridge basic and clinical sciences, state-of-the-art methodologies, and public health research approaches, in order to address pressing prevention research problems that require multi-disciplinary, integrated research strategies.

This program announcement is responsive to recommendations from the Institute of Medicine (Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research) and the National Prevention Conference (The Prevention of Mental Disorders: A National Research Agenda). It also addresses recommendations outlined under "The National Plan for Research on Child and Adolescent Mental Disorders."

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. The PA, Preventive Intervention Research Centers, is related to the priority areas of suicide and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private for-profit and non-profit domestic organizations such as universities, colleges, hospitals, laboratories, research institutions, units of State or local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Applications may be submitted using the developing center (P20) and mature center (P30) funding mechanisms. Support for a Developing PIRC (P20) may be requested for a single, non-renewable five-year period only, with a maximum request of \$300,000 per year, plus negotiated institutional indirect costs. Support for a Mature Center (P30) can be requested for renewable five-year funding periods, with a maximum request of \$1,000,000 per year, plus negotiated institutional indirect costs.

Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of an award will also vary.

RESEARCH OBJECTIVES

Background

Since 1982, the NIMH has supported a number of Preventive Intervention Research Centers (PIRCs) with the aim of providing productive research environments where teams of investigators from a variety of disciplines would interact and develop focused programs of research on the prevention of mental and behavioral disorders and dysfunctions, and the promotion of mental health. To date, the PIRCs have included both infrastructure or core functions, as well as support for a set of interrelated research projects. Under the current announcement, PIRCs will move to a core function model; Center grants will cover cross cutting research functions such as data management, field coordination, and research planning and development activities around a substantive theme or set of themes. Costs for fully developed projects emerging from the Centers will be covered through regular research grant mechanisms.

PIRC Characteristics and Functions

Although the specific structure and organization of individual Centers will vary, all PIRCs are expected to help build the field of mental health prevention and promotion research by providing scientific leadership, an environment of research excellence, and models of community outreach and collaboration.

To fulfill the mission outlined above, PIRCs are expected to perform a number of critical functions. These functions may be represented as individual core units of the Center, or they may be clustered together. In either case, all of the functions must be addressed in PIRC applications, although the relative emphasis of functions may vary from site to site. Functions include, but are not limited to:

- o Research agenda and theory development. PIRCs are expected to develop an organizing prevention/promotion research theme or set of themes and a research agenda that define the mission of the Center. For each theme, PIRC applications are expected to review the relevant empirical and theoretical literature, identify major unresolved issues, and present a plan for developing a rigorous, theory driven, multi-disciplinary research program to address these outstanding questions and clarify theory.

- o Methodology. PIRCs are expected to provide state-of-the-art, sophisticated methodological expertise to all Center related research projects. This function includes, but is not limited to, sample development, methods and instrument development, assessment and diagnosis, research design, statistics, and primary and secondary data analysis. PIRCs can also support relevant biological and behavioral research laboratories.

PIRCs are strongly encouraged, where appropriate, to include a focus on methodological research aimed at solving design and statistical problems of critical importance to longitudinal field trials.

- o Data management. PIRCs are expected to provide state-of-the-art data management efforts in order to facilitate all aspects of data processing and analysis, and timely production of research publications.

- o Knowledge and technology transfer. PIRCs are expected to sponsor meetings and symposia in their thematic area, produce a variety of scientific publications and other outreach activities to disseminate findings and successful intervention technologies, and highlight ethical issues in preventive intervention research.

- o Mentoring. PIRCS are expected to provide prevention research scientist opportunities to new and established investigators. Special attention should be given to the recruitment of minority investigators. Centers are encouraged to apply for grants available to support developing scientists.

The number of personnel awarded will depend upon the capacity of the Center's scientists, but will not exceed 15 percent of the awarded direct costs for the Center.

- o Opportunities for research collaboration. PIRCs are strongly encouraged to capitalize on opportunities for cross site and cross research project collaborations, where appropriate. Collaborative research planning activities, including piloting, can be included as PIRC sponsored activities. Fully developed collaborative projects will be funded through regular research grant mechanisms.

- o Community sanction/liaison. PIRCs are expected to develop and disseminate model processes for achieving community sanction and cultural competence for all aspects of prevention field experiments.

Developing and Mature Centers

There are two categories of grant applications under the PIRC program: applications for Developing Centers (P20) and applications for Mature Centers (P30). Although there is no absolute criterion to distinguish who should apply in which

category, the following guidelines apply:

o The category of Developing Centers (P20) is appropriate for institutions that are either (a) interested in developing a critical mass of research scholars necessary to conduct state-of-the-art prevention research, or (b) already have a critical mass of researchers from relevant disciplines, who are interested in re-focusing and integrating their research around a preventive intervention theme. Applicants in this category must have strong track records in research (although not necessarily in prevention research) and show promise of developing into fully functioning prevention research Centers.

Developing Centers have research themes and existing collaborations, but need funds to recruit additional scientists, expand core functions, or fully develop a multi-disciplinary prevention research agenda.

Each Developing PIRC will provide research experiences for at least two preceptees annually, to be selected from scientific disciplines related to the goals of the Center. Preceptorships are defined as supervised research experience. Each Center should relate functionally with relevant departments of professional and graduate schools, as are appropriate to the needs of the preceptees.

o Mature Centers (P30) are fully developed entities that have the capacity to rapidly become mature, state-of-the-art research Centers by virtue of previous commitments of institutional resources, recruitment and/or development of an existing critical mass of prevention research scholars, the presence of substantial recent prevention publications in peer-reviewed research journals, active preventive intervention research grants, etc.

In Mature PIRCs, funds can be requested to support research career development candidates at the same level of experience as would be appropriate for NIMH-supported scientist development and academic awards.

Specific Research Topics

In keeping with the public health mission of prevention research, PIRC research programs will generally focus on randomized controlled intervention trials, but may include studies that span the entire scientific continuum. For example, PIRCs can include generative risk factor and model building research to inform theory on the etiology and development of psychopathology (hypothesis development). The research program can also include methods development relevant to the design and testing of a new intervention model, or to the development of innovative design and analytical approaches for the field as a whole. Centers are also strongly encouraged to include cost-effectiveness and cost-benefit studies wherever appropriate in their research agenda.

Intervention trials should be of two types: experimental tests of efficacy (controlled intervention trials of new intervention strategies) and of effectiveness (testing of efficacious interventions in controlled trials involving representative, defined populations.) Because of their logistical and methodological complexities, tests of effectiveness are particularly appropriate for inclusion in PIRC research programs. Similarly, PIRCs are encouraged, where appropriate, to include in their research programs plans for dissemination and/or services research once interventions have demonstrated effectiveness and are ready for adoption by service systems.

Centers may direct their efforts to well defined single, multiple, or co-morbid conditions, and test intervention strategies aimed at individuals and/or families, schools, communities, service systems, or other relevant domains. The following are examples of areas within this framework that might serve as a focus for Centers. The list is neither exhaustive, nor exclusive:

- o Development of prevention trials aimed at changing risk factors and/or mediators associated with mental disorder and pre-clinical behavioral dysfunctions in children, adolescents, and their families.
- o Methodologic development and experimental testing of promotive interventions, with emphasis on identification and independent assessment of relevant mental health outcomes.
- o Establishment of prevention trials aimed at risk factors common to a number of disorders and/or maladaptive outcomes.
- o Generation of ecologically valid prevention trials with multiple intervention components that target risk and protective factors across a number of domains simultaneously.
- o Development of trials aimed at understanding optimal timing or scope of interventions, or subgroup differences in response to different intervention strategies.
- o Generation of prevention trials involving embedded universal, selected, and indicated intervention strategies.
- o Development of multi-component intervention strategies through systematic testing of individual modules which are later tested in combinations.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4

of the Research Plan AND summarized in Section 5, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

It is strongly encouraged that potential applicants contact the Centers program staff very early in the planning process.

NIMH staff will offer each potential applicant advice and information regarding program relevance and purpose so that applications will comply with administrative requirements, meet program standards, and contain sufficient information to permit an adequate Center program review.

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard center application deadlines as indicated in the application kit. The number and title of this Program Announcement, Preventive Intervention Research Centers, PAR-94-038, must be typed in item number 2a on the face page of the PHS 398 application form. PHS regulations concerning application page-length apply to PIRC applications. In general, 25 pages of text are allowed for each core and research component of the Center. A submitted application will be reviewed within the category that it requests (i.e., Developmental or Mature); the IRG will not change categories as part of its review. Applicants should note that the metric system of measurement must be used if weights and measures are involved in the proposed research.

Application kits containing the necessary forms and instructions are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

The signed original and five legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established phs referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the National Institute of Mental Health, in accordance with the standard NIH peer review procedures.

The following criteria will be considered when assessing the merit of a PIRC application: intrinsic merit of the proposed intellectual focus and research agenda, appropriateness of the Center approach, presence of high-quality research investigators from several fields, Center Director qualities, adequacy of research resources and environment, quality and appropriateness of the infrastructure and research career development components of the PIRC's activities, appropriateness of PIRC organization, quality of Center functions, adequacy of plans to achieve community sanction, feasibility and budget, inclusion of women and minorities, adequacy of protection of human and animal subjects.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed work. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

All PIRC applications will be reviewed according to the procedures and criteria outline above. However, for the special case of applications for Developing PIRCs, the above criteria will be modified by the following: the nature and level of resource commitments from the home institution/department and from other participating institutions/departments are of necessity not of the level of the Mature PIRC; the quality of plans to recruit excellent new research faculty, or

to further integrate the work of existing investigators around preventive intervention trials; the likelihood that the establishment of a Developing PIRC will facilitate existing research activities and serve as a mechanism to expand the proposed prevention research theme into a fully developed prevention research agenda.

Following scientific-technical review, the application will receive a second-level review by the National Mental Health Advisory Council.

AWARD CRITERIA

Applications received in response to this announcement will compete with others submitted to NIMH for funding. In granting awards, the following criteria are considered:

- o Program relevance
- o Quality of application as documented by IRG and Council recommendations
- o Program balance
- o Availability of funding
- o Institute priorities

Grants must be administered in accordance with the PHS Grants Policy Statement (rev. October 1, 1990).

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Doreen Spilton Koretz, Ph.D.
Prevention Research Branch
Parklawn Building, Room 10-85
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4283

For further information on grants management issues, applicants may contact:

Diana Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-15
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.242, Mental Health Research Grants. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This announcement is not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100, or Health Systems Agency Review.

ARTICULATION DISORDERS OF UNKNOWN ORIGIN IN CHILDREN

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PA NUMBER: PA-94-039

P.T.

National Institute on Deafness and Other Communication Disorders

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) encourages research project applications to examine systematically the linguistic, phonologic, motoric, perceptual, cognitive, and other variables that have been posited to play a role in the genesis of articulation disorders of unknown origin in children. Research grant applications that address the nature of the disorder, subgroups within the disorder, and appropriate methods of prevention, diagnosis, and treatment of the disorder are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Articulation Disorders of Unknown Origin in Children, is related to the priority area of clinical prevention services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST)

(R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The support mechanisms for grants in this area will be the investigator-initiated research grant (R01) and the FIRST (R29) award. The NIH policies and submission dates that govern these mechanisms will prevail.

RESEARCH OBJECTIVES

Background

One of the most common communication disorders in childhood is that of errors in speech sound production (articulation). It has been estimated that articulation disorders represent in excess of 75 percent of all speech disorders in children. A large number of these articulation disorders have no recognizable organic, neurogenic, or physical correlate. Children with articulation disorders of unknown cause constitute 99 percent of the caseloads of speech-language pathologists working in the schools. Importantly, these difficulties may have consequences throughout the lifespan of these children.

Research on articulation disorders of unknown cause has focused on consideration of such variables as intelligence, motor skill, auditory discrimination, auditory memory, academic performance and socio-economic status, in an attempt to identify a causal link. The clinical observation that individual differences exist among these children and that effective intervention may depend on early identification and consideration of these relevant individual differences suggests that a number of complementary research perspectives be considered.

Traditionally, these disorders have been viewed as a possible motor disorder: a difficulty in the motor control of articulation and the coordinated, connected production of speech sounds. More recently, this view has been extended to include the general processing, organization and cognitive representation of linguistic information. Within this viewpoint, children's speech productions are seen as manifestations of underlying forms and phonological processes. Because of their presumed importance in early phonetic learning, speech discrimination deficits have also been considered to be potentially important factors in the development and perpetuation of such articulation disorders. Models of adult neurogenic speech disorders have also been applied to this group of misarticulating children in an attempt to examine the role that a difficulty in programming the speech musculature for volitional production of phonemes might play in children with articulation disorders. The diagnostic label of developmental apraxia of speech derives from this model. This term has been used to describe the speech behavior of children with moderate to severe articulation disorders of nonorganic cause.

Research Goals and Scope

Although no causal relationships have yet been determined, possible causes have been proposed, and models that could explain the nature of the articulation disorder have subsequently been developed. As a result, several theoretical approaches to articulation disorders of unknown cause have emerged. Most propose that one strong causal factor may be accompanied by other less strong but still influential factors contributing to the disorder. Although a number of insights have been gained by considering these children from these different perspectives, many issues remain.

Studies that may be proposed in applications submitted in response to this PA include, but are not limited to, the following:

- o Development of model systems of identification and evaluation of children with articulation disorders that consider the linguistic, phonologic, motoric, and cognitive aspects of normal development.
- o Identification of factors that place children at risk for developing articulation disorders and at risk for long-term problems of articulation.
- o Exploration of genetic factors associated with the development of articulation disorders of unknown cause.
- o Evaluation of acoustic-phonetic features of children's speech in order to identify predictors of subsequent articulatory disorders.
- o Delineation of subgroups of children with articulation disorders of unknown cause, using broad and interdisciplinary examinations of the linguistic, cognitive, motoric, perceptual, neurogenic, and genetic bases of the disorder.
- o Identification of appropriate techniques for the differential diagnosis and effective treatment of subgroups of this population.
- o Development, evaluation and standardization of improved phonological, motor and linguistic assessment and treatment procedures based on theoretical models.
- o Generation of incidence and prevalence data related to articulation disorders of unknown cause across age levels.
- o Determination of factors that enhance or diminish the efficacy of treatment for children with the disorder.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and females in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and females in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific

Islanders, African Americans, Hispanic Americans). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials. The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific questions addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard applications deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248. The title and number of the announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program priorities among research areas of the announcement.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Beth Ansel, Ph.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-C
Rockville, MD 20892
Telephone: (301) 402-3461

Direct inquiries regarding fiscal matters to:

Ms. Sharon Hunt
Grants Management Branch
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Suite 400-B
Rockville, MD 20892
Telephone: (301) 402-0909

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.173. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

GENE THERAPY IN DUCHENNE MUSCULAR DYSTROPHY

NIH GUIDE, Volume 23, Number 7, February 18, 1994

PA NUMBER: PA-94-040

P.T. 34; K.W. 0715140, 0745032

National Institute of Neurological Disorders and Stroke
National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) encourage the submission of research grant applications to investigate the potential for gene therapy in Duchenne muscular dystrophy. Responses to this program announcement may include studies in appropriate animal models of gene replacement using viral vectors, myoblast transfer, or other means of dystrophin enhancement.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000," a PHS-led national activity for setting priorities. This program announcement, Gene Therapy in Duchenne Muscular Dystrophy, is related to the priority area chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are eligible to apply for only regular research project grants (R01). Applications from minority individuals and women are encouraged.

MECHANISMS OF SUPPORT

The support mechanisms for grants in this area will be the investigator-initiated research project grant (R01), the First Independent Research Support and Transition (FIRST) award (R29), the program project grant (P01), and the center grant (P50). The Principal Investigator or program director, as well as any participating investigators, will plan, direct, and perform the research. Applicants for program project grants are requested to contact the NINDS representative listed below as early as possible in the planning stages.

RESEARCH OBJECTIVES

Duchenne muscular dystrophy (DMD) is the most common inherited neuromuscular disease, affecting approximately one in 3,500 male births. The disease is characterized by muscle necrosis and regeneration. Eventually, the regeneration cannot keep up with the necrosis, resulting in progressive muscle fiber loss. Affected boys are usually wheelchair-bound by age 12, with death occurring in the third decade. A milder variant, Becker muscular dystrophy, occurs once in 30,000 male births. Isolation of the X-linked DMD gene led to the discovery of dystrophin, the protein that is missing or defective in Duchenne muscular dystrophy and abnormal in Becker muscular dystrophy. Dystrophin is a 427-kd protein and an essential component of the inner surface of the sarcolemmal membrane. The full-length gene for dystrophin is huge, 2.4 megabases, and most mutations are frame-shift deletions (Duchenne) or internal in-frame deletions (Becker).

The most frequently studied animal model of Duchenne muscular dystrophy is the mdx mouse, in which the homologous mutation also results in a lack of dystrophin. Like affected humans, the mdx mice have recurrent muscle fiber necrosis; regeneration, however, is very efficient, and the mice do not suffer generalized muscle fiber loss and weakness. A dog model with a similar mutation may be a superior model of DMD because its size and symptoms are much closer to humans. Unfortunately, the dog model has several disadvantages compared to the mouse, including slow breeding rate, scarcity, and expense.

Among the potential genetic therapy approaches to dystrophin replacement that have been considered are direct injection of DNA, vector-mediated delivery, and myoblast transfer. These approaches all present major obstacles that must be overcome.

The full-length dystrophin gene with its associated promoters and other regulatory elements may be too large to routinely introduce into muscle fibers directly or using a viral vector. Human cDNA, length about 14 kb, has been isolated, and a partial cDNA of only 6.3 kb has been cloned from a patient with only very mild symptoms, suggesting that such a smaller "minigene" could protect DMD muscles from necrosis. A gene of this size could be accommodated in an adenovirus or retrovirus vector.

Myoblast transfer studies in mice have been reported, with the percentage dystrophin positive host muscle fibers varying widely. Several groups of investigators have also performed similar experiments in Duchenne muscular dystrophy boys. The procedure appears to be safe, but so far there is little evidence of increased strength or the production of dystrophin in the host muscle.

This announcement solicits applications for any study whose ultimate goal is the successful genetic therapy of Duchenne muscular dystrophy. Examples are given below, but applications are not limited to these areas of research:

- o Improve methods to express dystrophin cDNAs in viral vectors, including adenovirus and retrovirus.
- o Develop techniques to increase the penetration of gene constructs into the muscle cells and their nuclei and to enhance the dispersion of injected gene constructs or myoblasts.
- o Develop strategies to enhance the efficiency of myoblast transfer therapy.
- o Investigate the feasibility of the 6.3 kb cDNA for genetic therapy.
- o Find alternative mechanisms to increase levels of existing dystrophin.
- o Assess the feasibility of injecting DNA directly into muscle cells.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Sections 1-4 of the research plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants. For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) according to instructions contained in the application kit. Application kits are available from most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248.

Check "YES" in item 2a on the face sheet of the application and type "Gene Therapy in Duchenne Muscular Dystrophy."

FIRST (R29) applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Applicants for the P01 or P50 should use the application format as described in the NINDS pamphlet, NINDS GUIDELINES: PROGRAM PROJECT AND RESEARCH CENTER GRANTS (rev. June 1992). Deadlines for the receipt of applications are February 1, June 1, and October 1. The completed original application and five exact copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

If the application is for a program project or center grant, submit the original and three copies to the Division of Research Grants. An additional two copies must be sent to Dr. Nichols at the address listed under INQUIRIES to expedite processing applications for multidisciplinary efforts.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants for regular research grants and FIRST awards, and by an appropriate institute committee for program projects and centers. A second level of review will be made by an appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be used in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Paul L. Nichols, Ph.D.
Developmental Neurology Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8C08
Bethesda, MD 20892
Telephone: (301) 496-5821

Richard W. Lymn, Ph.D.
Muscle Biology Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 594-9959
Bitnet: LYMANIHCU

Direct inquiries regarding fiscal matter to:

Patricia P. Driscoll
Grants Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 10A14
Bethesda, MD 20892
Telephone: (301) 496-9231

Carol Clearfield
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 726
Bethesda, MD 20892
Telephone: (301) 594-9973

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.853 ("Clinical Research Related Neurological Disorders") and 93.854 ("Biological Basis Research in the Neurosciences"). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-150, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***



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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 8
February 25, 1994

RICHARD W. MURRY

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

NOTICES

RESEARCH GRANT SUPPLEMENTS FOR INDIVIDUALS WITH DISABILITIES

NIH GUIDE, Volume 23, Number 8, February 25, 1994

P.T. 34; K.W. 0730000

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) will make supplemental funds available to grantees to extend research opportunities to individuals with qualifying disabilities who are capable of entering a research career. It is hoped that the supplemental funding will increase the number of individuals with disabilities participating in health services research.

Supplemental awards are available to support individuals with disabilities who are either graduate students, postdoctoral researchers, or faculty. Application, for or acceptance of, a research supplement does not alter the requirement that grant recipients must not exclude from participation in any program receiving Federal financial assistance an otherwise qualified, disabled individual solely by reason of the disability. In addition, grant recipients must make reasonable accommodation to the known physical or mental limitations of an otherwise qualified disabled individual unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of the recipient's program.

General Provisions

The proposed research experience must be an integral part of the approved, ongoing research of the parent grant. Individuals with disabilities must be given the opportunity to interact with individuals of the parent grant, contribute intellectually to the research, and enhance their research skills and knowledge concerning health services research. Furthermore, the Principal Investigator must demonstrate a willingness and understanding that the purpose of the award is to enhance the research capability of the student or faculty member with a disability, and the research experience is intended to provide opportunities for individuals with disabilities to develop into independent, competitive research investigators.

Principal Investigators are encouraged to contact their project officer or the AHCPR grants management officer prior to submission in order to obtain specific information about application requirements. It is recognized that individual circumstances vary and, for unusual situations, the grants management officer should be consulted for a determination of eligibility.

Reasonable Accommodations

Funds may be requested, as part of the supplemental application, to make changes or adjustments in the research setting that will make it possible for an otherwise qualified employee with disabilities to perform the essential functions associated with his/her role in the project. The accommodations requested under this program must be directly related to the performance of the proposed role on the research project and must be appropriate to the disabilities of the individual. Some types of accommodations that might be provided under these awards include: specialized equipment; assistive devices; and personnel such as readers, interpreters, and assistants. In all cases, the total funds for accommodations requested from the supplement must be reasonable in relationship to the direct costs of the parent grant and the nature of the supplemental award.

ELIGIBILITY REQUIREMENTS

To be eligible for a supplemental award, the Principal Investigator must hold an active AHCPR research grant (R01, R18, R29, or U01) with a minimum of two years research support remaining at the time of application. Principal Investigators must be performing their research in domestic institutions.

Usually, each parent grant may have only one supplement for a person with disabilities. Appointment of more than one individual to a single grant under this program will be considered depending on the nature of the parent grant, the circumstances of the request, and the program balance of AHCPR. A supplemental award under this program does not preclude a separate supplement to support an underrepresented minority. It is not necessary for the individual with disabilities to be appointed full time.

There is a ceiling of supplemental funds available which is 20 percent of the awarded direct costs. That ceiling includes administrative supplements, minority supplements, and supplement under this program. For example, an award of \$200,000 for the parent grant could receive up to a total of \$40,000 for the sum of an administrative supplement, a minority supplement, and/or a supplement under this program.

Eligible Candidates

For the purpose of this announcement, the definition of disabled individuals in the Americans With Disabilities Act will be used. An individual with a disability is one who has (A) a physical or mental impairment that substantially limits one or more major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment." Qualified individuals with disabilities are those who, with reasonable accommodation for their disability, are capable of entering a research career after appropriate experience and training. Disabilities that might confer eligibility for supplemental awards under this program include, but are not limited to, the following: total deafness in both ears, visual acuity less than 20/200 with corrective lenses, speech impairment, missing extremities, partial paralysis, complete paralysis, convulsive disorders, mental or emotional illness, learning disabilities, kidney dialysis, and severe distortion of limbs and/or spine. In all cases, individuals supported under this supplement program must, with reasonable assistance, be able to contribute to the research supported by the parent grant.

The supplemental application may request support for a graduate student or a faculty member who is interested in the field of health services research. Awards will be limited to citizens, non-citizen nationals, and individuals who have been lawfully admitted for permanent residence (i.e., in possession of an Alien Registration Receipt Card) at the time of application.

Individuals with disabilities may receive support under this program on only one grant at a time but may be supported by more than one grant during the development of their research careers. Support under this supplemental program is not transferable to another individual.

This program is not intended to provide an alternative means of supporting disabled individuals who are already supported by research grants or other Public Health Service (PHS) mechanisms. If a Principal Investigator wishes to transfer an individual with disabilities to supplemental support from an existing PHS-supported position, the reason for the transfer must be clearly documented. Individuals may not be transferred to supplemental support merely to increase the availability of funds on the parent grant. Disabled individuals receiving National Research Service Award (NRSA) support may not be transferred to supplemental support prior to the completion of their appointed period of training.

APPLICATION PROCEDURES

A request for a supplemental award may be received at any time. Grantee institutions must make requests on behalf of the Principal Investigator of the parent grant and in cooperation with the disabled individual(s) who will participate in the grant. Grantee institutions should submit the request for supplemental funds using the face page, budget pages 4 and 5 and a narrative justification from grant application form PHS 398 (rev. 9/91). The proposed budget should be related to the percent effort of the disabled individual. For graduate students or faculty the salary requested must be in accordance with the salary structure of the institution and consistent with the level of effort. Funds may also be requested to permit accommodations to the research environment.

Applicants should include a brief three to four page description, prepared by the Principal Investigator, of each disabled individual's role in the ongoing research project. The description should summarize how the experience will be expected to enhance the research capabilities of the disabled individual and how it relates to the research objectives of the parent grant. There should be a signed statement from the individual with disabilities describing how the research experience will relate to his/her educational objectives and research goals. The individual's academic and scientific experience should be described and the individual's curriculum vitae and social security number included.

The Principal Investigator must demonstrate that each individual with disabilities has made a commitment to the ongoing research project. Finally there should be a statement that establishes the eligibility of the individual with disabilities for support under this program. This should include information certifying: the individual's citizenship; the nature of the disability; any occupational limitations associated with the disability; and the types of accommodations, currently existing or yet needed, that will permit the individual to undertake the proposed research experience. The institution should indicate its contribution to aid accommodation of the candidate to the research environment.

If the initial budget period requested is for less than 12 months, the budget should be prorated accordingly.

REVIEW CONSIDERATIONS

AHCPR will review requests for supplements using the following criteria: (1) The qualifications of the individual with disabilities including career goals, prior research training, relevant experience, and potential for a research career after appropriate experience and training. (2) The degree to which the individual's role in the project would result in an educational experience of future benefit to the individual. (3) The degree to which the individual's role in the project will contribute to the scientific objectives of the project. (4) The degree to which the individual's proposed efforts are integrated with those of others on the research team. This includes the nature, quality, and frequency of interaction the individual is expected to have with the others on the team. (5) The degree to which any research design or logistical modifications of the project are sound and contribute to the research objectives of the parent grant. (6) The appropriateness of the proposed accommodations for the candidate and the appropriateness of the cost of the proposed accommodations relative to the cost of the parent project and the nature of the requested supplement with evidence that the proposed accommodations, including those provided by the grantee institution, will be sufficient to enable the candidate to adapt to the research environment.

AWARD CRITERIA

AHCPR may approve, disapprove, or approve with modifications any application for a supplement for an individual with disabilities. Based on the availability of funds, quality of applications, and furtherance of the stated objectives, AHCPR may award supplemental funds in a lesser amount than requested and for less than the full number of participants proposed.

The decision to fund a supplement will be made four to six weeks from the time the request is submitted. Within the current budget period, funds will be provided as an administrative supplement to the parent grant. Continued funding for the supplement should be requested as part of the non-competing continuation application, with a separate budget page showing the supplemental funds requested. Approval will be contingent on (1) funding of the parent grant, (2) the progress in reaching the objectives of the supplement, and (3) the retention of the individual with disabilities in the project. The supplement may not extend beyond the current non-competitive segment of the parent grant.

INQUIRIES

Principal Investigators interested in participating in this program are encouraged to contact either their project officer or:

Ralph L. Sloat
Grants Management Office
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MC 20852-4908
Telephone: 301-594-1447

PHS GRANTS AND CONTRACTS ORIENTATION COURSE

NIH GUIDE, Volume 23, Number 8, February 25, 1994

P.T. 34; K.W. 0710030

Public Health Service

SUMMARY

The Office of the Assistant Secretary for Health is announcing a training course entitled "Orientation to PHS Grants and Contracts Activities for Applicants and Recipients of Awards" which will be presented 12 times at locations around the country between April 1994 and March 1995. Complete information about locations and dates is provided below under SUPPLEMENTARY INFORMATION.

SUPPLEMENTARY INFORMATION

COURSE TITLE - "Orientation to PHS Grants and Contracts Activities for Applicants and Recipients of Awards." **NOTE:** This is not a course on grant-writing. Rather, it is designed to provide a broad overview of how to conduct business with the PHS using the grant and contract mechanisms.

COURSE DESCRIPTION

This is a two-day course that is designed to provide applicants for and recipients of PHS grants and contracts a better understanding of the procedures and expectations in applying for funding and administering an award from the PHS. Day one and roughly 25 percent of day two of the course concentrate on the grants process; the remainder of day two is devoted to contracting. Students will be provided with a broad overview of conducting business with the PHS including how it is organized, when the grant or contract mechanism is used, how the PHS contracts and grants processes are structured, how to identify grant and contract funding opportunities, how to submit effective proposals and applications, and how to properly administer a contract or grant once it has been awarded. This is not, however, a course on "grantsmanship" or writing technical proposals.

TARGET POPULATION

Grant and contract staff of organizations that are presently doing business with the PHS or plan to submit applications for grants or proposals for contracts. The course is intended for staff who are inexperienced with PHS grant and contract mechanisms.

COURSE DATES AND LOCATIONS

| DATE | LOCATION |
|------------------------|-------------------|
| April 21-22, 1994 | Washington, DC |
| May 12-13, 1994 | Boston, MA |
| June 30 - July 1, 1994 | Denver, CO |
| August 8-9, 1994 | Kansas City, MO |
| August 25-26, 1994 | Chicago, IL |
| September 26-27, 1994 | San Francisco, CA |
| September 29-30, 1994 | Seattle, WA |
| November 9-10, 1994 | Washington, DC |
| December 12-13, 1994 | San Diego, CA |
| January 17-18, 1995 | Dallas, TX |
| February 21-22, 1995 | Atlanta, GA |
| March 6-7, 1995 | Washington, DC |

All sessions will be held from 8:30 AM to 4:30 PM both days. Early registration is encouraged, since past offerings of this course have filled rapidly.

COURSE OUTLINE

DAY 1

o Introduction to PHS Assistance (grants/cooperative agreements) and Acquisition (contracts): PHS Mission and Organizational Structure; Assistance vs. Acquisition (The Federal Grant and Cooperative Agreement Act); PHS Grant and Contract Expenditures and Recipients; Introduction to Types and Purposes of PHS Grants; Roles of PHS Grants and Program Management Staff.

o Seeking and Applying for PHS Grants/Cooperative Agreements: Sources of Information; Understanding Program Announcements; The Application Package; The Complete, Effective Application; Competition and Objective Review.

o Negotiation and Award Process for Grants/Cooperative Agreements: Cost Analysis and Preaward Review; Negotiation--Clarifying and Revising Proposed Activities; Funding Outcomes; Contents of a Grant Award Document; General and Special Conditions.

DAY 2

o Grant/Cooperative Agreement Post-Award Issues and Concerns: Monitoring; Audit; Appeals; Progress Reports; Drawdowns; Financial Status Reports; Grant Budget Control; Cost Principles and Unallowable Costs; Purchasing; Property Management.

o Seeking PHS Contracts: Identifying PHS Contracting Opportunities; The Legal Framework of PHS Contracting; Small Business Contracting Programs; Roles of PHS Contracting and Project Staff.

o Responding to Contract Solicitations: Small Purchases - \$25,000 or Less; Purchases Greater Than \$25,000; Preparing the Technical Proposal; Preparing the Business Proposal.

o Proposal Submission, Contract Negotiation, and Award: Submitting the Proposal; Evaluation of the Proposal; Negotiation; Award of Contract

o Contract Administration: Initial Contract Administration Steps; Significant Contract Administration Concerns.

CLASS SIZE Limited to 30 participants per session to maximize interaction.

ATTENDANCE Students are encouraged to attend both full days of the course. A Certificate of Attendance will be issued to those who complete the course.

COST Tuition is \$295 per session. Travel and accommodations are the responsibility of participants.

INQUIRIES

For information on how to register and to receive a copy of the course brochure, contact:

John Laffey
Management Concepts Incorporated
8230 Leesburg Pike, Suite 800
Vienna, VA 22182
Telephone: (703) 790-9595, ext. 140
FAX: (703) 790-1371

EXTRAMURAL ASSOCIATES RESEARCH DEVELOPMENT AWARD

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFA: OD-94-003

P.T. 14, FF; K.W. 1014006, 1014002

National Institutes of Health

Application Receipt Date: May 2, 1994

PURPOSE

The Extramural Associates (EA) Program is soliciting applications from academic institutions with significant minority student enrollment, and from women's colleges for participation in the January or June 1995 sessions of the EA Program. In addition, the award will enable the participating institution to establish or enhance an office of sponsored research and to provide for other research infrastructure needs.

ELIGIBILITY

Eligibility is limited to those domestic academic institutions that have a significant enrollment comprised of minorities (i.e., African Americans, Hispanics, Asians, Native Americans), or are women's colleges, and have a faculty member who has not participated in the NIH Extramural Associates Program since 1991.

INQUIRIES

Further information may be obtained from:

Mr. Theodore W. Blakeney, Jr.
Office of Extramural Programs
National Institutes of Health
Building 31, Room 5838
Bethesda, MD 20892
Telephone: (301) 496-9728

DETERMINATION OF PROTECTIVE LEVELS OF MATERNAL ANTIBODY AGAINST EARLY ONSET INVASIVE GROUP B STREPTOCOCCAL DISEASE IN NEONATES

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFP AVAILABLE: NICHD-DESPR-94-06

P.T. 34; K.W. 0745045, 0715125

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) plans to conduct a study that will recruit two groups of infants <7 days of age: infants who have developed invasive GBS (Type Ia, Ib, II and III) disease ("cases"), and infants who have not developed early onset GBS despite being born to GBS-colonized mothers ("controls"). GBS disease will be defined as an infection associated with isolation of GBS from normally sterile sites, such as cerebrospinal fluid and blood. A total of 240 cases and 960 controls will be recruited from participating hospitals over a period of two years. Cases will be identified by active laboratory-based surveillance, and controls will be identified through a systematic culturing of about five percent of parturient mothers in the participating hospitals. To be eligible, both cases and controls must be singleton births of at least 34 weeks' gestation, born to mothers who have not received antibiotic treatment during pregnancy.

This Request for Proposals (RFP) for the detection of GBS is a new acquisition. The release of the RFP will be on or about March 1, 1994 and proposals will be due 60 days thereafter.

INQUIRIES

A short-form version of the RFP will be provided first, which includes only the Statement of Work and Evaluation Criteria to be used for selection of the awardee. After examining this, a full-text version of the RFP must be requested, in writing, for those organizations interested in responding. Those organizations desiring a copy of the above short-form RFP may send their written request to:

Mrs. Lynn Salo
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 7A07
Bethesda, MD 20892

All requests must cite the RFP number above and include two self-addressed mailing labels for the short-form and complete RFP. All sources who consider themselves qualified are encouraged to submit a proposal. This announcement does not commit the Government to awarding a contract.

MAINTENANCE AND OPERATION OF SYNTHETIC PEPTIDE FACILITY

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFP AVAILABLE: NICHD-CD-94-07

P.T. 34; K.W. 0760060, 1003006, 0780017

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute for Child Health and Human Development (NICHD), has a requirement for maintenance and operation of a synthetic peptide facility capable of synthesizing gram-scale quantities (1-50 grams) of peptides for toxicology studies, primate testing, and clinical investigation, as well as small quantities (5-100 milligrams) of new peptides for initial biological testing in small animals.

Offerors should have expertise in the synthesis of peptides (by solid phase techniques), especially those of MW>1000, on a small scale and on a large scale as noted above. Specific assignment of peptides and quantities to be prepared will be determined by the Project Officer. Major emphasis will be on the preparation of peptides on a gram-scale (1-50 grams). The Contractor's facilities must meet the requirements for Good Manufacturing Practices (GMP) inasmuch as GMP must be followed for all peptides prepared for toxicology and clinical studies. The Contractor may be required to supply all gram-scale batches (1-50 grams) of peptides at a minimum purity of 97 percent. The minimum purity requirements for small quantities (5-100 mg) of peptides is anticipated to be 93 percent. The Contractor will furnish, package, and distribute all peptides synthesized under the contract, as requested by the Project Officer, in the amounts designated, together with evidence of purity and characterization including but not limited to HPLC, TLC, optical rotation, quantitative amino acid analysis, mass spectral analysis, NMR, and mixed and parallel chromatograms of the peptide(s) against the standard peptide(s) to be furnished by the Project Officer. A functional group analysis by TLC spray reagent, and evidence of electrophoretic homogeneity may also be required as well as sequence analysis of the peptides. An additional requirement for peptides prepared under GMP will be water, salt and C, H, & N analysis (including ash content) and an estimation of peptide content. No subcontracting will be permitted.

As a minimum requirement, the Contractor's facilities must meet requirements in compliance with OSHA for protection of its workers. The Contractor's facilities must be operated in accordance with current Good Manufacturing Practices (GMP) issued by the FDA. Whenever necessary, the Contractor will be expected to prepare an Application for Drug Master File (to be submitted to the FDA) relevant to the peptides synthesized under the contract. The Government estimates the effort to be approximately 3.40 technical staff years annually. The Principal Investigator should be an established peptide chemist and should devoted approximately 15 percent effort to the project. All responsible sources may submit

a proposal which will be considered by the agency.

It is anticipated that one cost-reimbursement incrementally funded type contract will be awarded as a result of the RFP for a period of (60) months, beginning November 30, 1994. The Request for Proposals (RFP) represents a recompetition of the project "Maintenance and Operation of a Synthetic Peptide Facility" being performed by the Salk Institute for Biological Studies, San Diego, California.

INQUIRIES

This announcement is not an RFP. RFP NICHD-CD-94-07 will be available on or about March 1, 1994. Proposals will be due approximately 60 days thereafter. Requests for the RFP must cite the above RFP number. Copies of the RFP may be obtained by sending a written or FAX request to:

Paul J. Duska
Contracts Management Branch
National Institute of Child Health and Human Development
6100 Building, Room 7A07
Bethesda, MD 20892
FAX: (301) 402-3676

IDIOPATHIC MALE INFERTILITY

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFA AVAILABLE: HD-94-015

P.T. 34; K.W. 0413002, 0705075

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: April 8, 1994

Application Receipt Date: May 18, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites research grant applications for the support of investigations comprising basic and clinical research on the etiology and pathophysiology of infertility in the otherwise normal male. Report language accompanying the House of Representatives 1994 appropriations bill encouraged NICHD to expand research activities in male infertility.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Idiopathic Male Infertility, is related to the priority area of family planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) (R29) award. Applications from minority individuals, persons with disabilities, and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01) and FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest expected award date is December 1, 1994.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

It is expected that up to four new awards will be funded, within the total direct cost limit of \$800,000 available for the first year. This level of support is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plan of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The overall objective of this RFA is to support and encourage research on the etiology and pathophysiology of infertility in men who are otherwise clinically normal. Laboratory research using human cells and tissues, and clinical research in human subjects, are invited under this RFA. Animal models will also be considered relevant if they can be justified as being applicable to human infertility. Examples of topics appropriate for this RFA might include, but not be limited to:

- o Subtle sperm function defects not being detected with existing methods;
- o Effects on fertility of immune sequelae following transient insult, e.g., postinfectious, postinflammatory, posttraumatic;
- o Physiological insult resulting in testicular dysfunction and subsequent impaired spermatogenesis;
- o Defective sperm-egg interaction;
- o Genetic abnormality manifested as early embryo loss.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 8, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Donna L. Vogel at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westward Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applications must be received by May 18, 1994. Late applications will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by DRG staff for completeness and by NICHD staff for responsiveness. If the application is not responsive to the RFA, it will be returned to the applicant. Responsive applications may be triaged by a peer review group to determine their relative competitiveness. The NIH will withdraw from further competition those applications judged to be noncompetitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further evaluation for scientific merit by an appropriate peer review group convened by the NICHD. Review criteria for RFAs are generally the same as those for unsolicited research grant applications. The second level of review will be provided by the National Advisory Child Health and Human Development (NACHHD) Council.

AWARD CRITERIA

The earliest anticipated date of award is December 1, 1994. Funding decisions will be based on peer review and NACHHD Council recommendations, program relevance, and availability of funds.

INQUIRIES

Direct requests for the RFA and inquiries regarding programmatic issues to:

Donna L. Vogel, M.D., Ph.D.
Center for Population Research
National Institute of Child Health and Human Development
Building 61E, Room 8B01
Bethesda, MD 20892
Telephone: (301) 496-6515
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 61E, Room 8B17
Bethesda, MD 20892
Telephone: (301) 496-5481
FAX: (301) 402-0915

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SUPERFUND HAZARDOUS SUBSTANCES BASIC RESEARCH PROGRAM

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFA AVAILABLE: ES-94-007

P.T. 34; K.W. 0725005, 1007003

National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: April 18, 1994

Application Receipt Date: June 17, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) is proposing the continuation of a special Program of basic research and training grants directed towards understanding, assessing, and attenuating the adverse effects on human health resulting from exposure to hazardous substances. Grants made under this Program will be for coordinated, multicomponent, interdisciplinary programs, and the objective is to establish and maintain a unique Program linking biomedical research with related engineering, hydrogeologic, and ecologic components.

The Superfund Amendments and Reauthorization Act (SARA) of 1986 established a university-based program of basic research within NIEHS. Accordingly, NIEHS will support projects in the areas of engineering, ecological, and hydrogeological research as long as they are to be performed in conjunction with biomedically related components. The NIEHS has encouraged true collaborative efforts among researchers in these various areas, and hopes to continue this endeavor. While emphasizing the necessity for a strong biomedical core, it intends that the nonbiomedical projects will be an integral part of the overall effort and not a support or core function.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Superfund Hazardous Substances Basic Research Program, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone (202) 783-3238).

ELIGIBILITY REQUIREMENTS

Section 311(a)(3) of SARA limits recipients of awards to "accredited institutions of higher education," which are defined in the Higher Education Act, 20 USC (annotated) 3381. However, grantees are permitted under the law, and encouraged by NIEHS, to subcontract as appropriate with an organization, public or private, necessary to conduct portions of the research. These organizations may include generators of hazardous wastes, persons involved in the detection, assessment, evaluation, and treatment of hazardous substances, owners and operators of facilities at which hazardous substances are located, and state and local governments.

MECHANISM OF SUPPORT

The mechanism of support will be the P42 multiproject grant-in-aid for a period not to exceed five years, starting in FY 95. Administrative adjustments may be necessary to make the funding periods coincide with this time frame. This program is not intended to support individual research project grants.

FUNDS AVAILABLE

This Program is being resolicited under the assumption that funds available will at least be equal to those of the current fiscal year (FY 94, \$32.9 million). For planning purposes, NIEHS estimates the funds (total costs) available for this solicitation for the first year of support for the entire Program \$35 million. The expected range of number of awards is 15 to 20.

RESEARCH OBJECTIVES

The NIEHS Superfund Hazardous Substances Basic Research and Training Program is intended to foster the growth of collaborative multidisciplinary research programs aimed at understanding health and environmental effects associated with hazardous waste sites and at developing improved technologies for cleaning up these sites. The focus of this Program is on the effects on human health.

Strong biomedical research is a requisite of this Program. A minimum of three approved biomedical projects is required for funding. The Program expects that the non-biomedical research will be an integral part of the overall effort. All applications considered for funding must contain approved projects in both biomedical and non-biomedical areas. Further, NIEHS intends to support graduate and advanced training in environmental and occupational health and safety, the engineering aspects of hazardous waste control, and geosciences in the setting of the research program.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 18, 1994, a letter of intent that includes the overall title of the proposed research, and a descriptive title of each of the proposed research projects that will be included in the application. Also provide the name, address and telephone number of the principal investigator, identities of other key personnel and consultants, participating institutions, and number and title of the RFA to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NIEHS staff to estimate the potential review work load and to avoid conflict of interest in the review. The letter of intent is to be sent to:

Ethel B. Jackson, D.D.S.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7826
FAX: (919) 541-2503

APPLICATION PROCEDURES

Applications must be received by June 17, 1994. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

REVIEW CONSIDERATIONS

Following NIEHS staff review for responsiveness to the objectives of this Program, applications will be reviewed and evaluated by a group of predominantly non-Federal consultants with expertise in fields relevant to the innovative research NIEHS is seeking to encourage. Applications that are complete and responsive may be subjected to a preliminary evaluation by a peer review group to determine their scientific merit relative to the other applications received in response to this RFA. As a result of this triage process, the NIEHS will withdraw from further consideration applications judged to be noncompetitive and promptly notify the Principal Investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit.

INQUIRIES

Written and telephone requests for the RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

William A. Suk, Ph.D., M.P.H.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0797

Direct inquiries regarding fiscal matters to:

Ms. Dorothy Williams
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-2749

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.143, NIEHS Superfund Hazardous Substances Basic Research and Education Grant Program. Awards will be made under authority of the Superfund Amendments and Reauthorization Act of 1986, Title 1, Section III, and Title II, Section 209 (Public Law 99-499); and Public Health Services Action, Section 301 (Public Law 78-410, as amended), and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This Program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFA AVAILABLE: AR-94-006

P.T. 34; K.W. 0740005, 0715010

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: April 15, 1994

Application Receipt Date: July 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) requests applications to initiate a pilot clinical study designed to test the hypothesis that intravenous antibiotic therapy is an effective and safe treatment for rheumatoid arthritis. The budget appropriation report language for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) indicated that funds were provided to "...initiate a pilot clinical trial to study the efficacy of intravenous antibiotic therapy in treating rheumatoid arthritis. This study should include measures of disease activity and, pending the outcome, be considered the initial step in developing a multicenter clinical trial."

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA/PA, title, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01). The total project period for applications submitted in response to the present RFA may not exceed two years. The anticipated award date is September 1994.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

A sum of \$500,000 (total cost) is available for this RFA. One award is anticipated. Of this amount, \$50,000 is reserved for the operation of a Data and Safety Monitoring Committee.

RESEARCH OBJECTIVES

Background

The role of infectious agents in the pathogenesis of rheumatoid arthritis is uncertain. In 1971 a small clinical trial of low dose tetracycline treatment for rheumatoid arthritis demonstrated no beneficial effect (Skinner et al., Arthritis Rheum 1971;14:727-35). In two small open trials oral minocycline appeared to improve outcome in rheumatoid patients (Breedveld et al., J Rheumatol 1990;17:43-6; Langevitz et al., J Rheumatol 1992;19:1502-4). In April 1991, the NIAMS initiated a double-blind, placebo-controlled clinical trial of oral minocycline. The results of this trial, as well as the results of a similar trial in the Netherlands, were presented at the 57th Annual Meeting of the American College of Rheumatology in San Antonio, Texas, on November 8, 1993 (Tilley et al., Arthritis Rheum 1993;36:s46 and Kloppenburg et al., Arthritis Rheum 1993;36:s47). The American study showed modest benefit and low toxicity, while the European study showed little benefit and moderate toxicity.

For many years the Senate Appropriations Committee has expressed an interest in the infectious theory of rheumatoid arthritis, especially the possibility that mycoplasma organisms cause rheumatoid arthritis. In its 1994 Appropriations Report, the Committee directed "that NIAMS, within the funds provided, initiate a pilot clinical trial to study the efficacy of intravenous antibiotic therapy in treating rheumatoid arthritis. The study should include measures of disease activity..." The NIAMS now solicits applications to fulfill this directive.

Goals and Scope

The goal of this RFA, accordingly, is to encourage development of a pilot clinical research project designed to test the hypothesis that intravenous antibiotic therapy is a potentially effective and safe therapy for RA.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Susana A.S. Sztein at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The applications should include detailed description and justification of the antibiotic regimens chosen. Special attention should be paid to describing how patients will be monitored for clinical activity and how patients will be monitored for toxicity, including opportunistic infections. Because patient safety is a paramount concern, an independent Data and Safety Monitoring Committee (DSMC) will be a required component of the study. Full instructions for the establishment of such a Board are available from Dr. Susana A.S. Sztein, at the address listed under INQUIRIES. The Food and Drug Administration (FDA) requires that Investigational New Drug (IND) approval be obtained if a drug is to be used for a non-label purpose. It is the applicant's responsibility to obtain such approval.

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grant Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NIH program administrator listed under INQUIRIES.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy L. Broadwater
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 406
Bethesda, MD 20892
Telephone: (301) 594-9979
FAX: (301) 594-9673

Applications must be received by July 13, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NIAMS. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIAMS staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Applications may be triaged by a peer review group convened by NIAMS on the basis of relative competitiveness. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIAMS. The second level of review will be provided by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Review criteria for RFAs are generally the same as those for unsolicited research grant applications.

- o scientific, technical, or medical significance and originality of proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of the resources necessary to perform the research;
- o appropriateness of the proposed budget and duration in relation to the proposed research; and

To ensure patient safety, the independence, composition, competence, and procedures of the DSMC will be considered among the review criteria.

AWARD CRITERIA

The anticipated date of award is September 30, 1994

Award criteria are:

- o priority score
- o availability of funds
- o safety monitoring

An award is contingent on NIAMS approval of the DSMC and on verification that an FDA IND approval has been obtained for the antibiotic(s) to be tested.

INQUIRIES

Written and telephone requests for the RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA, inquiries regarding programmatic issues and requests for guidelines for the DSMC to:

Dr. Susana A.S. Sztein
Rheumatic Diseases Branch,
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 594-9953
FAX: (301) 594-9673

Direct inquiries regarding fiscal matters to:

Mrs. Diane M. Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 732A
Bethesda, MD 20892
Telephone: (301) 594-9965
FAX: (301) 594-9950

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis and Musculoskeletal and Skin Diseases Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ADDENDUM

BREAST CANCER RESEARCH PROGRAMS IN NCI-DESIGNATED CANCER CENTERS

NIH GUIDE, Volume 23, Number 8, February 25, 1994

RFA: CA/ES/AG-94-005

P.T. 34; K.W. 0715036

Application Receipt Dates: February 17, 1994 and March 29, 1994

This notification provides a second receipt date for submission of applications in response to RFA CA/ES/AG-94-05. Applications will be accepted on the original receipt date of February 17, 1994, and March 29, 1994. The purpose of providing additional time is to allow all potential applicants to consider addressing two additional areas in their applications. These areas pertain to (1) the need to include in the application a discussion of the involvement of the Cancer Center and Director in continuing oversight of the developing breast cancer program and (2) an opportunity to include a research subtheme focussed on Long Island breast cancer research issues.

Applicants who have submitted applications for the February 17 receipt date may submit an addendum with information pertaining to either or both of the areas only. The addendum should be clearly identified with the title of the project in the original grant application and submitted on or before March 29 to:

Dr. Gail Bryant
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 635-J
Bethesda, MD 20892
Telephone: (301) 402-0801

INQUIRIES

For further information, applicants may contact:

Dr. Margaret E. Holmes
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 502
Bethesda, MD 20892
Telephone: (301) 496-8531
FAX: (301) 402-0181

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816



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NIH GUIDE

For Grants and Contracts

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National Institutes of Health

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Building 31, Bethesda, Maryland 20892

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AND HUMAN SERVICES**

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 9
March 4, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

NOTICES

EXTENSION OF COOPERATIVE AGREEMENT: THE NICHD STUDY OF EARLY CHILD CARE

NIH GUIDE, Volume 23, Number 9, March 4, 1994

P.T. 34; K.W. 0404004, 1014006

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) has an active interest in the support of research on the development of children who have been placed in child care arrangements during their infancy. In 1988, NICHD issued a request for cooperative agreement applications (RFA) titled "Effects of non-parental infant day care on child development." The data collection for the study that ensued will terminate at the end of 1994 and NICHD intends to extend this cooperative agreement for an additional five years for the purpose of longer follow-up studies of the same cohort of children. It also intends to limit the competition to the participating research sites and to expert investigators who have access to the study participants and to data derived therefrom. The study will continue to be conducted as a collaboration between awardees and NICHD scientific program staff. The NICHD staff will have substantial programmatic involvement in designing and coordinating the research protocol, monitoring its progress, making data analyses plans and writing scientific papers. The NICHD scientific program staff member will also continue to be responsible for the overall coordination of the project.

INQUIRIES

Additional information may be obtained from:

Sarah L. Friedman, Ph.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Building 61E, Room 4B05
Bethesda, MD 20892
Telephone: (301) 496-6591
FAX: (301) 402-2085
Bitnet: SF2@NIHCU

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

THE NIH GUIDE FOR GRANTS AND CONTRACTS: INTENT TO MODIFY

NIH GUIDE, Volume 23, Number 9, March 4, 1994

P.T. 34; K.W. 1014006, 1004017

National Institutes of Health

PURPOSE

The National Institutes of Health intends to modify the NIH Guide for Grants and Contracts on August 1, 1994. The format of Request for Applications (RFAs) and Program Announcements (PAs) will not be changed, but increased emphasis on electronic access of those documents will be implemented. The purpose of the changes is to improve the timeliness and accuracy of information dissemination and reduce production costs.

BACKGROUND

The printed edition of the weekly NIH Guide for Grants and Contracts now includes notices, PAs, Notices of Availability (NA) of RFAs, and NAs of Requests for Proposals (RFP) and is mailed to approximately 34,000 subscribers. Although first class postal service is used, copies of the printed version may not be received until a week or more following publication.

Currently, a delimited, electronic edition of the NIH Guide, which includes RFAs in addition to NA/RFAs, is sent via a BITNET LIST to 530 sites, primarily university offices of sponsored research. The NIH Guide is also available on a public access electronic bulletin board and on the NIH GOPHER on the Internet. Through these sources, the NIH Guide, including the full text of RFAs and PAs, is available nationwide within a day of publication.

INTENDED MODIFICATIONS

Content of the NIH Guide

The printed edition of the NIH Guide will contain notices and brief NA/RFAs and NA/PAs. The NAs will include a brief summary of the purpose of the RFA or PA; the application receipt date, anticipated number of awards, and funds available for RFAs; and information about how to obtain a copy of the RFA or PA. The electronic edition will include the contents of the printed edition and the complete text of PAs and RFAs.

Access to the NIH Guide

PAs and RFAs will be available in print and via email from the NIH contacts listed in each NA in the printed edition. The NIH will send one copy of the printed edition of the NIH Guide to each major component of each Institution, primarily to the Offices of Sponsored Research or the equivalent, and institutions not on the list of institutional contacts maintained by the NIH may request subscriptions. The current subscription list for the printed edition will be terminated.

The electronic edition of the NIH Guide, including the RFAs and PAs, will be available to individuals via a LISTSERV subscription list, the NIH Grant Line electronic bulletin board, and the NIH Gopher Server. Current subscribers to the printed edition are encouraged to establish a preferred route to the electronic edition of the NIH Guide as soon as possible and cancel subscriptions to the printed edition.

ELECTRONIC ACCESS TO THE NIH GUIDE FOR GRANTS AND CONTRACTS

LISTSERV Distribution

On the day of publication, a delimited electronic edition of the NIH Guide for Grants and Contracts is distributed to list members. The delimiters are characters that mark the beginning and end of each item. Several institutions have found this useful for topical searching, archiving, and intra-institutional distribution. At this time, individuals and institutions may join the list. To join, send an E-mail message to Q2C@NIHCU.bitnet or via the Internet to Q2C@CU.NIH.GOV requesting inclusion on the list.

NIH Grant Line Bulletin Board

The NIH Grant Line includes information about NIH extramural programs, including the NIH Guide for Grants and Contracts. A new feature on the NIH Grant Line allows the rapid transmission of files via Bitnet or Internet to a Bitnet or Internet address instead of downloading via a modem.

To access the NIH Grant Line, the terminal emulator must be configured as follows: 1200 or 2400 baud, even parity, 7 data bits, 1 stop bit, half duplex. Using the procedure specified in the communication software, dial 1-301-402-2221. When a response indicates that a connection has been made, type ,GEN1 (the comma is mandatory) and press ENTER; the NIH system will prompt for INITIALS?. Type BB5 and press ENTER. A prompt will ask for ACCOUNT? Type CCS2 and press ENTER.

Messages and a menu will be displayed that allow one to read Bulletins and download Files. Back issues of the NIH Guide are found in different Directories. GUIDE90 has issues going back to July 6, 1990; GUIDE91, GUIDE92, and GUIDE93 have all issues for each year. Type F (for FILES) to access any of the files that are arranged into directories. To get an overview of the kinds of information available, type D (for Directory).

Access to NIH Grant Line via the Internet

To access the NIH Grant Line in an interactive Internet session, Telnet to WYLBUR.CU.NIH.GOV and, when a message has been received that the connection is open, type VT100. At the INITIALS? prompt, type BB5 and at the ACCOUNT? prompt, type CCS2. This puts the user into the NIH Grant Line.

NIH Gopher

The NIH Gopher contains information about the NIH, including the NIH Guide to Grants and Contracts, and has text searching capability. One can tunnel to the NIH Gopher, if one has access to a system with Gopher. Local computer support staff should be consulted for additional information.

INQUIRIES

For additional information or comment on the intended modifications, direct inquiries to:

Claudia Blair, Ph.D.
Director, Institutional Affairs Office
National Institutes of Health
Building 1, Room 328
Bethesda, MD 20892
Telephone: (301) 496-5366
FAX: (301) 402-2831
email: ubl@nihcu.bitnet or ubl@cu.nih.gov

For additional information about the NIH Grant Line Bulletin Board, direct inquiries to:

John C. James, Ph.D.
Assistant Director for Special Projects
Division of Research Grants
Westwood Building, Room 109
Bethesda, MD 20892
Telephone: (301) 594-7270
FAX: (301) 594-7384

MINORITY SCIENTIST AWARD AT MINORITY INSTITUTIONS

NIH GUIDE, Volume 23, Number 9, March 4, 1994

RFA AVAILABLE: ES-94-006

P.T. 34, FF; K.W. 0725005

National Institute of Environmental Health Sciences

Application Receipt Date: May 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Human health and human disease result from three interactive elements: Environmental factors, genetic susceptibility, and age. The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by further understanding each of these elements and how they interrelate. The ultimate goal of the NIEHS activities is to define and understand the mechanism of action of environmental agents on human health, and to transfer this knowledge to the public benefit.

The NIEHS invites minority faculty members at historically black colleges and universities and other predominantly minority colleges, universities and health professional schools to submit applications for support of activities directed at the development of investigators at such schools in areas relevant to environmental health sciences. The intent of the award is to provide an underrepresented minority faculty member with increased access to research opportunities through collaborative arrangements with funded environmental health scientists.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Minority Scientist Award at Minority Institutions, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325 (telephone (202) 783-3238).

ELIGIBILITY REQUIREMENTS

A minority school is defined as a medical or nonmedical college, university or equivalent school in which students of minority ethnic groups including African Americans, Hispanics, American Indians, and Asian or Pacific Islanders comprise a significant proportion of the school enrollment.

Candidates for this award are full-time underrepresented minority faculty members at a minority institution who (1) are members of an underrepresented minority group; (2) are citizens of the United States, noncitizen nationals, or permanent residents at the time of application; (3) have an M.D., Ph.D. degree or equivalent in a biomedical or behavioral science; (4) wish to develop research capabilities in environmental health sciences research; and (5) have the background and potential to become an independent biomedical investigator. A minimum of 70 percent effort annually must be committed to the award.

Each candidate must also identify and complete arrangements with a mentor, preferably at a majority or minority institution within reasonable commuting distance, approximately 100 miles, who is recognized as an accomplished, independently funded investigator in the research area proposed, and who will provide guidance for the awardee's development and research plan. Preference will be given for applications with a mentor who is an NIEHS-supported researcher. NIEHS staff is willing to assist prospective applicants in identifying appropriate NIEHS grantees. The plans for an intensive training period should be developed with the mentor.

The commitment of the mentor and his/her institution to both summer and academic year training must be evidenced by letters of support to be included in the application. A commitment from the mentor's department head must be included in the application.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) Minority Scientist Award at Minority Institutions (K14). Applicants will be responsible for the planning, direction, and execution of the proposed project. Awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000 (rev. October 1, 1990). Awards are nonrenewable and nontransferable from one awardee to another. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year. In addition, funding for the fourth and fifth years is dependent upon the submission of applications for traditional NIH grant support (R01, R29, R15) or other grant programs not specifically targeted to minority institutions. Awards should be requested for a period of five years.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for this RFA are anticipated to be \$250,000. It is expected that two to three awards will be possible. This level of support is dependent on the receipt of a

sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

This program is designed to support environmental health sciences related research career development of minority faculty at minority institutions at the M.D., Ph.D. or equivalent level who have the interest and capabilities of doing state-of-the-art research in this area.

The objective of this RFA is to broaden the experience of faculty members at minority schools, to increase the pool of biomedical and behavioral investigators in environmental health sciences research, and to inform undergraduate students, most of whom will be minority individuals, about research opportunities in environmental health sciences.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must be received by May 20, 1994. If an application is received after that date, it will be returned to the applicant.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies, to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete and non-responsive applications will be returned to the applicant without further consideration. Applications may be triaged on the basis of relative competitiveness. Those applications judged to be competitive will undergo further merit review by an appropriate review group convened by the Scientific Review Branch, NIEHS. The second level review by the National Advisory Environmental Health Sciences Council considers the special needs of the NIEHS and the priorities of the NIEHS Program.

The review factors that will be used in the evaluation of applications for this RFA are listed below.

- o The overall merit of the candidate's plan for research and the development of research skills.
- o The background and potential of the proposed candidate for development into an independent biomedical investigator.
- o The candidate's commitment to a research career.
- o The ability of both the minority institution and the training center to provide facilities, resources, and opportunities necessary for the candidate's research development.
- o The commitment of the home institution to the faculty candidate's research and development
- o The arrangement between the applicant and mentor for the conduct of the research.
- o The qualifications, ability, and plans of the mentor who will provide the candidate with the guidance necessary for career development in research. Recognition of the mentor as reflected by receipt of support from national peer reviewed funding sources.
- o The schedule and plans for the submission of traditional NIH grant applications.
- o The seminar plan.

INQUIRIES

The NIEHS welcomes the opportunity to clarify any issues or questions from potential applicants. Written and telephone inquiries concerning this RFA are encouraged. However, potential applicants are expected to have reviewed the material in the RFA before contacting the NIEHS.

To receive a copy of the RFA, contact the NIEHS either by FAX at (919) 541-2843 or Voice Mail at (919) 541-3319. Include the complete mailing address and telephone number.

Direct mail requests for a copy of the RFA to:

Michael J. Galvin, Jr., Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-02 (North Campus)
Research Triangle Park, NC 27709

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Winters
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 2-01 (North Campus)
Research Triangle Park, NC 27709

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.113 and 93.115. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 43 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

SUPPLEMENTS TO PROMOTE REENTRY INTO BIOMEDICAL AND BIOBEHAVIORAL RESEARCH CAREERS

NIH GUIDE, Volume 23, Number 9, March 4, 1994

PA NUMBER: PA-94-040

P.T. 34; K.W. 0710030

National Institute of Mental Health

PURPOSE

The National Institute of Mental Health (NIMH), National Institutes of Health (NIH), announces a program for administrative supplements to research grants to support individuals with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other family responsibilities. The aim of these supplements is to encourage fully trained individuals to reenter research careers within the missions of all the program areas of NIMH. This program will provide administrative supplements to existing NIMH research grants for the purpose of supporting full-time or part-time research by these individuals in a program geared to bring their existing research skills and knowledge up to date.

The NIMH recognizes the need to increase the number of women and minorities in basic, behavioral, and clinical science research careers. Among the reasons for the low representation of women may be the fact that women bear a majority of the responsibilities surrounding child and family care. To address this issue, this program is designed to offer opportunities to individuals, especially women, who have interrupted their research careers to care for children or parents or to attend to other family responsibilities. The objective of the program is for those who receive support to reestablish careers in mental health-related research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Supplements to Promote Reentry into Biomedical and Biobehavioral Research Careers, is related to the priority area of women's health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Grants and Cooperative Agreements: Only the following active NIMH award mechanisms at domestic institutions are eligible for the Supplement to Promote Reentry into Biomedical and Biobehavioral Research Careers: R01, R10, R18, R24, R37, P01, P50, U01, U10. Principal Investigators on such awards are invited to submit a request for an administrative supplement to the awarding component of the parent grant to support an eligible candidate interested in reestablishing a research career. The parent grant must have at least two years of support remaining at the time of the proposed beginning date of the supplemental funding. The rationale for this policy is to assure ample opportunity for the candidate to develop further her or his research skills. A maximum of three years supplemental support can be awarded under this program. Usually, a parent grant would support only one administrative supplement (Research Supplements for Underrepresented

Minorities, Research Supplements to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers, or Research Supplement to Promote Reentry into Biomedical and Biobehavioral Research Careers). Grants most likely to support more than a single administrative supplement are multicomponent awards.

Candidates

Candidates must have a doctoral degree, such as M.D., D.D.S., Ph.D., D.V.M., or equivalent, and at least two years of post-doctoral research experience and must have had sufficient prior research experience to qualify for a faculty appointment at the assistant professor or equivalent level. Candidates who have begun the reentry process through a fellowship or similar mechanism are not eligible for this program.

The duration of the career interruption must be for at least two years. Examples of qualifying interruptions would include starting and/or raising a family; an incapacitating illness or injury of the candidate, the spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service. The program is not intended to support graduate or postdoctoral training and is not intended to support career changes from non-research to research careers for individuals without prior research training. At the time of application, a candidate may not be engaged in paid research activities for more than 10 hours per week.

MECHANISM OF SUPPORT

In all cases, the proposed research must be directly related to the approved ongoing research of the parent grant or cooperative agreement. The individual supported under this supplemental award, hereafter called the reentry candidate, must be afforded the opportunity to act as a full participant in the research project and must be given an opportunity to update and enhance her or his research capabilities. This will allow the candidate to establish a career as an independent, competitive research investigator. Supplemental awards will be consistent with the goals of strengthening the existing research program and with the overall programmatic balance and priorities of the funding program of the NIMH. Awards will be made according to the policies and provisions stated in this announcement and in the PHS Grants Policy Statement (rev. 10/90).

Administrative supplements (S1) provided under this program may be for either part-time or full-time support for the candidate, and all supported time is to be spent updating and enhancing research skills. Proposed part-time appointments may not be less than 20 hours per week.

Supplemental awards may be made for up to three years and may not exceed \$50,000 in direct costs per year. A maximum of \$40,000 may be requested for the combination of full time salary and fringe benefits for the reentry candidate. Proposed part-time appointments may not be for less than 20 hours per week (continuous) and must be pro-rated accordingly. The amount of salary requested must be consistent with the policies of the grantee institution for individuals occupying similar positions (up to our maximum annual limits) and must relate to the percent of effort and number of months requested for the supplement. An additional amount up to \$10,000 may be requested for supplies, domestic travel, and publication costs relevant to the proposed research. Equipment may not be purchased as a part of this supplement without justification and specific prior approval of the NIMH.

The decision to fund a supplement will take six to eight weeks from the time the necessary information is received. During the first budget period, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on funding of the parent grant and can not extend beyond the current competitive segment of the parent grant.

FUNDS AVAILABLE

It is expected that approximately \$150,000 will be available from NIMH to support three Reentry Administrative Supplements during Fiscal Year 1994.

APPLICATION PROCEDURES

A request for a supplement may be made at any time during the funding year, providing there will be two full years of funding remaining for the parent grant at the time of funding. In making requests, the grantee institution, on behalf of the Principal Investigators, should submit the request for supplemental funds directly to the program official of NIMH responsible for the parent grant. Principal Investigators should obtain the address for submission from the NIMH program administrator for the parent grant. Applications should not be sent to the Division of Research Grants address provided on grant application form PHS 398 (rev. 9/91).

The request for a supplemental award must include the following:

1. A complete face page (with appropriate signatures) from grant application form PHS 398 (rev. 9/91), including the title and grant number of the parent grant and "Reentry Supplement" on line 1
2. A brief, three- or four-page description, prepared by the Principal Investigator of the parent grant, that includes:
 - a. A summary or abstract of the funded grant or project
 - b. A description of the research proposed for the candidate
 - c. How the supplement will expand and foster the independent research capabilities of the candidate
 - d. How the proposed research relates to the specific research goals and objectives of the parent grant
 - e. A description of the scope and nature of the mentoring relationship between the Principal Investigator and the candidate
3. A brief description, prepared by the candidate, that includes:
 - a. research objectives and career goals
 - b. length of and reason for career hiatus
 - c. description of how the candidate has kept current in her/his field

d. identification of steps taken toward reentry, (if any, such as attending scientific meetings)

4. A biographical sketch of the candidate that includes:

- a. curriculum vitae
- b. social security number
- c. citizenship status
- d. publications
- e. other evidence of scientific achievement.

5. A proposed budget entered on budget pages from the grant application form PHS 398 (rev. 9/91), related to the percent effort for the research proposed for the reentry candidate during the first and future budget period(s) (The amount requested for the supplement must coincide with the current period of support. Thus, if the initial budget period requested is less than 12 months, the budget must be prorated accordingly.)

6. Documentation, if applicable, that the proposed research is approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) of the grantee institution

7. Under unusual circumstances where the applicant and mentor would be at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must also be submitted.

The request must be signed by the Principal Investigator, the reentry candidate, and the appropriate institution business official.

REVIEW CONSIDERATIONS

The program staff of the particular awarding component will review requests for supplements using the following general criteria:

- o the qualifications of the reentry candidate, including career goals, prior research training, research potential, and any relevant experience
- o the plan for the proposed research experience in the supplemental request and its relationship to the parent grant
- o evidence from the Principal Investigator that the experience will enhance the research potential, knowledge, and/or skills of the reentry candidate
- o evidence from the Principal Investigator that the activities of the reentry candidate are an integral part of the project
- o evidence of excellence of prior research training and experience of the reentry candidate
- o evidence of effort by the reentry candidate to initiate the reentry process, such as attending scientific meetings, keeping current with journals
- o evidence that proposed research will achieve the stated objectives of the reentry supplements

In noncompeting continuation applications, the progress report for the reentry supplement should be clearly delineated from the progress report for the parent grant. The progress report should include information about the research activities supported by the supplement, even if support for future years is not requested.

Since these applications will undergo administrative review, summary statements will not be produced. This is consistent with NIH practice for other similar programs, such as those referenced in the ELIGIBILITY REQUIREMENTS section of this program announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Reentry candidates who have not yet made contact with a Principal Investigator will be referred to the program official whose Division or program is specific to their research interest.

Direct inquiries regarding programmatic issues to:

Deborah Dauphinais, M.D.
Office for Special Populations
National Institute of Mental Health
5600 Fishers Lane, Room 17C-14
Rockville, MD 20857
Telephone: (301) 443-3724

To discuss business aspects of the parent grant or the supplement, Principal Investigators may contact their grants management official. For other information concerning grants management issues, applicants may contact:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fisher Lane, Room 7C-15
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.242, 93.281, and 93.282. The statutory authorities for these supplements are Sections 301, 487, and 518 of the Public Health Service Act. (42 U.S.C. 241, 288, and 290cc-11), as amended. Federal regulations at 42 CFR Part 52, "Grants for Research Projects" and 45 CFR Part 74, "Administration of Awards," are applicable to these awards. Grants must be administered in accordance with the Public Health Grants Policy Statement.

ACADEMIC AWARD IN ENVIRONMENTAL/OCCUPATIONAL MEDICINE

NIH GUIDE, Volume 23, Number 9, March 4, 1994

PAR NUMBER: PAR-94-041

P.I. 34; K.W. 0725007, 0725020

National Institute of Environmental Health Sciences

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) announces its fifth national competition for Environmental/Occupational Medicine Academic Awards (E/OMAA), which last appeared in the NIH Guide, Vol. 22, No. 14, April 9, 1993. The award will have the dual purpose of improving the quality of environmental/occupational medicine curricula and fostering graduate research careers in environmental/occupational medicine. For the purposes of the E/OMAA, the term environmental/occupational medicine refers to the area of medicine concerned with the development of knowledge and the application of knowledge directed at the diagnosis, treatment, and prevention of adverse human health effects from environmental/occupational exposures to toxic agents. This includes adverse health effects in infants, children, and adults who are at risk of developing such health problems and the reduction of preventable complications or disability in persons of all ages who have already developed such diseases.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Academic Award in Environmental/Occupational Medicine, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only schools of medicine or osteopathy in the United States and its possessions or territories are eligible to compete for Environmental/Occupational Medicine Academic Award for a project period that does not exceed five years and, if successful, to receive the Award once only.

MECHANISM OF SUPPORT

Mechanism of support for this activity will be for the research career program (academic) (K07) award.

RESEARCH OBJECTIVES

The NIEHS initiated the E/OMAA Program to provide a stimulus for development of an environmental/occupational medicine curriculum in those schools that do not have one and to strengthen and improve the environmental/occupational medicine curriculum in schools that do. Awards provide support to applicant faculty members for their educational development and for implementation or expansion of the curriculum in environmental/occupational medicine.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application deadline date is June 1, 1994.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248 (one copy), and 301/594-7378 (for multiple copies). The title and number of the program announcement must be typed in Section 2a on the face page of the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for technical merit by a special study section convened by the NIEHS in accordance with the standard NIH peer review procedures. Following technical review, the applications will receive a second level review by the National Advisory Environmental Health Sciences Council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications in the Career (K) category assigned to the NIEHS. Applications will be evaluated for evidence of commitment by both the sponsoring institution and the sponsoring department or division to the accomplishment of the objectives of the award, as well as the qualification, interest, and commitment of the candidate to undertake the responsibility for implementing a high quality environmental/occupational medicine curriculum. Additional criteria are included in the program guidelines available from NIEHS program staff.

INQUIRIES

Program Guidelines for the E/OMAA award are available. Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Annette G. Kirshner, Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-03 (North Campus)
Research Triangle Park, NC 27709
Telephone: (919) 541-0488

Direct inquiries regarding fiscal matters to:

David L. Mineo
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
National Institutes of Health
P.O. Box 12233, North Campus
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.894. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

FELLOWSHIP AND CAREER AWARDS IN SICKLE CELL DISEASE RESEARCH

NIH GUIDE, Volume 23, Number 9, March 4, 1994

PAR NUMBER: PAR-94-042

P.T. 22; K.W. 0715032

National Heart, Lung, and Blood Institute

PURPOSE

The objective of this program announcement is to encourage the submission of applications for Fellowship and Clinical Investigator Development Awards in Sickle Cell Disease research in order to support the training and professional development of individuals who can serve the expanding research, teaching, and clinical requirements in the area of sickle cell disease. This program announcement emphasizes the need for increased research training and career development in this area and encourages individuals at varying levels of experience to submit applications for support by using three existing research training and career development mechanisms that are sponsored by the NHLBI.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Fellowship and Clinical Investigator Development Awards in Sickle Cell Disease Research, is related to the priority areas of clinical prevention services, chronic disabling conditions, and maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-782-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities colleges, hospitals, laboratories, units of State and local governments and eligible agencies of the Federal government. Only domestic institutions are eligible for K awards. At the time of application for a fellowship or K award, individuals must be either citizens or noncitizen nationals of the United States or have been lawfully admitted to the United States for permanent residence. An individual lawfully admitted for permanent residence must submit with the application a notarized statement indicating possession of the alien Registration Receipt Card (1-151 or 1-551). Individuals on temporary or student visas are not eligible.

MECHANISM OF SUPPORT

The mechanisms of support available for this program announcement are the NRSA Individual Fellowship (F32), NRSA Senior Fellowship (F33) and the Clinical Investigator Development Award (CIDA) (K08).

The three support mechanisms for Fellowship and Clinical Investigator Development Awards in Sickle Cell Disease provide a wide range of training and career development opportunities to obtain research experience in sickle cell disease. A brief description of these mechanisms is listed below.

NSRA Individual Fellowship Award (F32)

Provides support for individuals at the postdoctoral level who wish to gain experience in biomedical and behavioral research related to sickle cell disease. Upon completion of this training, individuals are encouraged to consider other mechanisms to support further research experience.

NRSA for Senior Fellows (F33)

Provides support to experienced scientists who have at least seven years of relevant postdoctoral research or professional experience and wish to make major changes in the direction of their scientific careers, or enhance and enlarge their capabilities to conduct biomedical and behavioral research on problems related to sickle cell disease.

Clinical Investigator Development Award (K08)

Provides support to physicians with varying levels of research experience to prepare them for research careers as independent investigators. Candidates' development programs are based on scholastic background, previous research experience, past achievements, and identified skills needed to become an independent scientist. The objective is to develop clinical investigators whose basic and clinical research interests are grounded in the advanced methods and experimental approaches needed to solve problems in sickle cell disease.

Detailed guidelines for each of the support mechanisms can be obtained from most institutional offices of sponsored research; the Office of Grants Information, Division of Research Grants, National Institutes of Health, telephone (301) 594-7248; and Dr. Fann Harding, Division of Blood Diseases and Resources, telephone (301) 496-1817.

RESEARCH OBJECTIVES

Background

Sickle cell anemia is a major health problem characterized by recurrent episodes of pain called "crises," a chronic anemia related to accelerated destruction of red blood cells, increased susceptibility to certain infections, and acute and chronic damage to various organs. This blood disorder results from the presence of genes for sickle hemoglobin inherited from both parents. In the United States, sickle cell anemia is predominantly, but not exclusively, found in persons of African ancestry. The prevalence of sickle cell anemia within this group is about 1 in 500 at birth, affecting more than 50,000 individuals in this country. This disorder is also found in Greeks, Southern Italians, Eti-Turks, Arabs, Egyptians, Southern Iranians and Asiatic Indians at incidence rates often equal to or greater than that found in African-Americans. In addition, sickle cell hemoglobin also occurs in combination with other abnormal hemoglobins and thalassemia, bringing the total number of individuals affected with various forms of sickle cell disease to over 70,000 in the United States. Thus, sickle cell anemia and related hemoglobinopathies are among the most common genetic blood disorders seen in this country.

During the past two decades, there has been a quantum leap in basic and clinical research leading to significant advances at the molecular and cellular levels. This progress embraces a number of important research areas, including the molecular structure of the sickle hemoglobin fiber, kinetics of polymerization, adherence of sickle cells to vascular endothelium, alterations in blood flow, regulation, and control of globin gene expression, development of animal models, abnormalities of the red cell membrane, and identification of genetic modifiers. At the clinical level, there appears to be a new era of therapeutic optimism, especially with agents that increase fetal hemoglobin, which are now undergoing clinical trials. Patients are living longer and more productive lives. Mortality from infection, the major cause of early death in infants and young children, has been significantly reduced with early identification of newborns with sickle cell disease and adding prophylactic penicillin to the management regimen. In spite of this progress to date, an effective therapy remains elusive.

These major advances in basic and clinical understanding of sickle cell disease provide an unprecedented opportunity for further improvements in patient management. In addition, the enormous health and economic impact of sickle cell disease, estimated to be more than \$705 million per year, argues strongly for increased attention to this disorder. A particular emphasis is placed on training due to the paucity of qualified investigators to carry out basic and clinical research as well as patient care in sickle cell disease. This need was reaffirmed by the NHLBI Sickle Cell Task Force convened to investigate the significant decline noted in investigator-initiated research in sickle cell disease. Although the Task Force was unable to ascribe the decline to any single factor, it made several recommendations to remedy this problem. These recommendations included the initiation of strategies to augment the availability of training and career development programs devoted to sickle cell disease. This Program Announcement is a direct response to that recommendation. The "Sickle Cell Task Force Report on Investigator-Initiated Research" was published in May, 1993.

Areas of Interest

The integration of a broad range of disciplines is required to further elucidate the basic pathophysiology of the disease and achieve the goals of treatment, prevention, and management. Thus, sickle cell disease is an especially exciting research area, encompassing a wide spectrum of scientific interactions with important behavioral and humanistic components. Potential research areas include cell biology, biochemistry, genetics, molecular biology, physiology, and psychology. Individual programs that offer research training and career development opportunities in all areas related to sickle cell disease are encouraged. The past training of candidates applying for these programs may have been in the basic sciences or in the clinical disciplines. If candidates do not possess skills in research design and biostatistics, the applicant should consider including these areas in his/her training or career development plan.

Candidates submitting applications in response to this program announcement should focus on topics exemplified by those listed below. These topics are examples only and should not be viewed as inclusive. Applicants are encouraged to consider other related topics and innovative approaches.

- o Basic research projects that lead to a better understanding of the pathophysiology and clinical manifestations of sickle cell disease.
- o Basic and applied research projects that lead to the development of effective therapeutic approaches for the treatment of sickle cell disease.
- o Clinical research projects that will improve the identification of patients at risk for severe disease and the development of methods and therapies to prevent sequelae.
- o Studies that deal with the psychosocial and behavioral aspects of sickle cell disease.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans, Blacks, and Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the application will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications for NRSA Individual Fellowships (F32) and Senior Fellowships (F33) are to be submitted on the grant application form PHS 416-1 (rev. 10/91) and will be accepted at the standard application deadlines as indicated in the application kit. Applications for Clinical Investigator Development Awards (K08) are to be submitted on PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application.

The completed original application, for a Clinical Investigator Development Award, and three legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications for NRSA Fellowships will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH. Applications for Clinical Investigator Development Awards, assigned to the NHLBI, will be reviewed by the appropriate initial review group managed by the Division of Extramural Affairs, NHLBI. All reviews will be conducted

in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

The review criteria are set forth in the guidelines for each support mechanism.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review.
- o Availability of funds
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Fann Harding, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 5A08
Bethesda, MD 20892
Telephone: (301) 496-1817

For fiscal and administrative matters, contact:

Ms. Jane R. Davis
Blood Division Grants Management Section
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15
Bethesda, MD 20892
Telephone: (301) 594-7436

AUTHORITY AND REGULATIONS

The programs of the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, number 93.839. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency review.

ERRATUM

MORE FACULTY DEVELOPMENT AWARD

NIH GUIDE, Volume 23, Number 9, March 4, 1994

PAR NUMBER: PAR-94-034

P.T. 14; K.W. 0710030

National Institute of General Medical Sciences

Application Receipt Dates: February 1, June 1, and October 1

The program announcement of the MORE Faculty Development Award (PAR-94-034) was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 7, February 18, 1994. The following paragraph concerning reference letters should be added to the announcement.

Letters of Reference

At least three sealed letters of reference must accompany the application. The references should address the candidate's qualifications and the potential impact of this award on the candidate's research and teaching potential. A list of individuals submitting reference letters must be included at the end of the research plan. Provide the name, title and institutional affiliation for each individual.

IDIOPATHIC MALE INFERTILITY

NIH GUIDE, Volume 23, Number 9, March 4, 1994

RFA: HD-94-015

P.T. 34; K.W. 0413002, 0705075

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: April 8, 1994

Application Receipt Date: May 18, 1994

The Request for Applications (RFA) HD-94-015, published in the NIH Guide for Grants and Contracts, Vol. 23, No. 8, February 25, 1994, contained an incorrect date for earliest possible award. The correct date is April, 1, 1995, not December 1, 1994 as published. The dates for receipt for letters of intent and applications are unchanged.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***



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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 10
March 11, 1994

RICHARD W MURRY

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

NOTICES

NATIONAL RESEARCH SERVICE AWARD (NRSA) STIPEND INCREASE

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T.

National Institutes of Health
Agency for Health Care Policy and Research
Health Resources Services Administration

Effective with all awards made on or after October 1, 1993, the following annual stipend levels apply to all individuals receiving support through institutional or individual National Research Service Awards (NRSA), including Minority Access to Research Career (MARC) and Career Opportunities in Research (COR) institutional research training grants. These awards are all made under the authority of Section 487 of the Public Health Service Act. The new stipends are as follows:

| Career Level | Stipend for FY 94 |
|----------------------------------|-------------------|
| MARC/COR Honors Undergraduates | |
| Freshmen/Sophomores | \$5,460 |
| Juniors/Seniors | \$7,656 |
| Predoctoral | \$10,008 |
| Postdoctoral Years of Experience | |
| 0 | \$19,608 |
| 1 | \$20,700 |
| 2 | \$25,600 |
| 3 | \$26,900 |
| 4 | \$28,200 |
| 5 | \$29,500 |
| 6 | \$30,800 |
| 7 or more | \$32,300 |

Stipend level adjustments can be made only on the award date of the fellowship or the appointment date of the trainee. THESE STIPEND LEVELS ARE EFFECTIVE ONLY FOR AWARDS MADE WITH FY 1994 FUNDS; no retroactive adjustments or supplementation of stipends with NRSA funds for awards made prior to October 1, 1993 is permitted. Awards made during the period between October 1, 1993 and the date of this announcement will be retroactively adjusted by the PHS awarding component. Institutions are permitted to supplement NRSA stipends from non-Federal sources according to their own formally established policies, as described in the PHS Grants Policy Statement.

The new stipend levels are to be used in the preparation of future NRSA institutional training and individual fellowship applications. They will be administratively applied to all applications now in the review process.

SINGLE ANNUAL RECEIPT DATE OF INSTITUTIONAL NRSA APPLICATIONS

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T. 44; K.W. 0720005

National Institute of Neurological Disorders and Stroke

Effective with the May 10, 1994 receipt date for National Research Service Award (NRSA) Institutional Research Training Grants (T32) applications, the National Institute of Neurological Disorders and Stroke (NINDS) will have a single annual receipt date for institutional NRSA applications (new, competing renewal, and supplemental). These applications will be accepted for the annual May 10 date only and will no longer be accepted for the January 10 and September 10 receipt dates. The reasons for this change to the single receipt date are: (1) funding decisions on the institutional NRSA applications are made annually at the January Council meeting and (2) an average of only two applications have been submitted for the January 10 and September 10 receipt dates in past years.

INQUIRIES

Any questions regarding this change in procedure may be directed to:

Mr. Edward M. Donohue
Deputy Director, Division of Extramural Activities
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188

NEW RESOURCES AVAILABLE FOR CONDUCTING RESEARCH ON AGING

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T. 34; K.W. 0710010, 1002002

National Institute on Aging

The National Institute on Aging (NIA), recognizing that most investigators have neither the facilities nor the fiscal resources needed to develop and maintain colonies of aged animals, has made provision of resources one of its highest priorities. Currently available resources include a cell repository, a nematode bank, rodent colonies, and non human primate colonies. This notice announces the availability of two new NIA supported resources.

Calorically-Restricted Rodent Resource

Calorically-restricted rodents from six months to 30 months of age are available. These animals are individually caged and food intake is restricted. Mouse genotypes available are the inbred strains C57BL/6 and DBA/2 and the hybrid stock of B6D2F1 (C57BL/6 x DBA/2).

INQUIRIES

For information on this resource contact:

Office of Biological Resource Development
National Institute on Aging
Gateway Building, Suite 2C231
Bethesda, MD 20892
Telephone: (301) 496-0181
FAX: (301) 402-0010

Obesity, Diabetes, and Aging Nonhuman Primate Resource

The Obesity, Diabetes, and Aging Nonhuman Primate Resource of the University of Maryland School of Medicine is being supported in part by the National Institute on Aging to provide a service to NIH-supported investigators.

A colony of 45 middle-aged and older rhesus monkeys is under study longitudinally and specimens can be obtained for the examination of questions related to obesity, diabetes, and aging processes.

INQUIRIES

For further information contact:

Barbara C. Hansen, Ph.D.
Obesity and Diabetes Research Center
School of Medicine
University of Maryland at Baltimore
MSTF 600, 10 S. Pine Street
Baltimore, MD 21201
Telephone: (410) 706-3168
FAX: (410) 706-7540

AVAILABILITY OF HUMAN FETAL TISSUE

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T.

National Institutes of Health

Human embryonic and fetal tissues are available from the Central Laboratory for Human Embryology at the University of Washington. The laboratory, which is supported by the National Institutes of Health, can supply tissue from normal or abnormal embryos and fetuses of desired gestational ages between 40 days and term. Specimens are obtained within minutes of passage and tissues are aseptically identified, staged and immediately processed according to the requirements of individual investigators. Presently, processing methods include immediate fixation, snap fixation, snap freezing in liquid nitrogen, and placement in balanced salt solutions or media designated and/or supplied by investigators. Specimens are shipped by overnight express, arriving the day following procurement. The laboratory can also supply serial sections of human embryos that have been preserved in methyl Carnoy's fixative, embedded in paraffin and sectioned at 5 microns.

INQUIRIES

Alan G. Fantel, Ph.D.
Department of Pediatrics RD-20
University of Washington
Seattle, WA 98195
Telephone: (206) 543-3373
FAX: (206) 543-3184
email: agf@u.washington.edu

NIH REGIONAL SEMINAR -- SPECIAL TOPICS

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T.

National Institutes of Health

SEMINAR DESCRIPTION

The National Institutes of Health (NIH) is sponsoring an NIH Regional Seminar on Special Topics May 18-19, 1994, at the Condado Plaza Hotel in San Juan, Puerto Rico. This seminar is being offered in conjunction with the Society of Research Administrators (SRA) Southern Section and the National Council of University Research Administrators (NCURA) Region III (Southeastern), whose combined regional meeting will be held on May 15-18, 1994 at the same location. This 1.5-day seminar will be of interest to both new and senior research administrators and investigators, focusing on special topics. The "NIH Update" will be offered during the regular program of the SRA/NCURA regional meeting.

The NIH seminar will begin at noon on May 18, with a Fundamentals Workshop. This workshop is designed for research administrators and investigators from minority and less research-intensive institutions. The workshop will cover organization of sponsored projects offices, the NIH award mechanisms, application process, peer review, and NIH research administration (grants management and program, pre- and post-award). Staff from established grantee institutions are also strongly encouraged to attend this workshop in order to join in the discussions, network with other participants, and to facilitate the interaction and dialogue during Thursday's workshop.

The full-day special topic workshop on May 19 will be on Project Monitoring -- Streamlining Research Administration. This workshop is intended to enable a dialogue between NIH staff and institutional officials regarding the requirements for proper stewardship of Federal funds, both from the agency perspective and the institutional perspective. Specifically, panel presentations by NIH and grantee institution staff, as well as a joint panel of both, will address such issues as project reporting (progress and financial), institutional and project-specific assurances, preaward costs versus deficit spending, change of scope, unobligated balances, rebudgeting, research integrity, the responsible conduct of research, and conflict of interest. SRA has agreed to produce a discussion paper featuring the highlights of this workshop.

SEMINAR LOGISTICS

Seminar Leader
Geoffrey Grant, Acting Director
Office of Policy for Extramural Research Administration (OPERA)

Seminar Coordinator (NIH)
Joellen Harper, NIH Grants Policy Office, 301/496-5967

Seminar Coordinator (SRA)
Frederick B. Mesler, Texas A&M Research Foundation, 409/845-8629

Seminar Registration
Advance seminar registration is required by May 2, 1994. For registration materials, send a fax that provides your name, institution, address, telephone number, and anticipated number of registrants to: Frederick B. Mesler, FAX: 409/845-7143. Allow 7 to 10 days for receipt of the materials.

Registration Fee
The registration fee for the 1.5-day NIH seminar is \$125. This fee includes the materials for both workshops, as well as lunch on Wednesday, the reception on Wednesday evening, and continental breakfast and lunch on Thursday.

Location
The seminar will be held at the Condado Plaza Hotel. Hotel reservations can be made directly by calling 800/624-0420 or 809/721-1000. A special room rate of \$120 is being offered to conference participants. The cut-off date is April 2, 1994. (After that date, the negotiated room rate cannot be guaranteed.) Reference the NIH Regional Seminar when making reservations.

NIH REGIONAL SEMINARS IN PROGRAM FUNDING AND GRANTS ADMINISTRATION

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T.

National Institutes of Health

This announcement is to give advance notice of two NIH regional seminars for academic researchers and new and senior research administrators that will be held in 1994. Each seminar will last two days. Discussions of current issues that affect NIH funding and grants administration will be featured.

A MIDWEST SEMINAR will be hosted by Northwestern University in Evanston, IL, on July 21-22, 1994. To request registration materials, call 708/491-3003 or send a fax that provides your name, institution, address, telephone number, and anticipated number of registrants to 708/491-4800. Registration materials will be mailed two to three months before the seminar.

A SOUTHWEST SEMINAR will be hosted by the University of New Mexico in Albuquerque, NM on November 17-18, 1994. To request registration materials, call 505/277-3942 or send a fax that provides your name, institution, address, telephone number, and anticipated number of registrants to 505/277-8604. Registration materials will be mailed two to three months before the seminar.

Although these seminars are located to be convenient to people from particular regions, interested individuals from other regions are welcome to attend. Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and medical centers are encouraged to attend.

INQUIRIES

If you have any questions about hosting a regional seminar, contact:

Ms. Joellen Harper
Office of Policy for Extramural Research Administration
National Institutes of Health
Building 31, Room 5B50
Bethesda, MD 20892
Telephone: (301) 496-5967
FAX: (301) 480-8443

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOP

NIH GUIDE, Volume 23, Number 10, March 11, 1994

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, Office for Protection from Research Risks is continuing to sponsor workshops on implementing the Public Health Service Policy on Humane Care and Use of Laboratory Animals. Each of the workshops scheduled for Fiscal Year 1994 will focus on a specific theme.

The workshops are open to institutional administrators, members of Institutional Animal Care and Use Committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs. Ample opportunities will be provided to exchange ideas and interests through question and answer sessions and informal discussions.

MIDWEST REGION

DATES: MAY 5-6, 1994

TOPIC: Training and Education: Institutional Improvement - Crisis Prevention

LOCATION

Stewart Center and Memorial Union, Campus of Purdue University

SPONSOR

Purdue University

REGISTRATION

Ms. Lisa D. Snider, Administrative Assistant
Laboratory Animal Program
Purdue University
1071 South Campus Courts-D
West Lafayette, IN 47907-1071
Telephone: (317) 494-7206
FAX: (317) 494-0793

FEE: \$150.00 - Regular; \$50.00 - Graduate Students/Post-Docs

DESCRIPTION: The general theme will focus on continuing education and training as mandated by the National Institutes of Health and USDA. The format will include panel discussions and concurrent breakout sessions. The group discussions will address occupational health; analgesia/pain/surgery; euthanasia; and tailoring the CET programs to specific audiences.

NORTHWEST REGION

DATES: AUGUST 4-5, 1994

TOPIC: Sharing Animal Welfare Responsibilities Between Affiliated Institutions

LOCATION

Portland Marriott Hotel, Portland, OR

SPONSOR

Department of Veterans Affairs

REGISTRATION

Margaret Doherty
Veterans Affairs Medical Center
Portland, OR 97201
Telephone: (503) 220-8262 Ext. 7610
FAX: (503) 273-5351
FEE: \$150 - Regular; \$100 - Students and Technicians

DESCRIPTION: The workshop will explore the relationships among academia, government, and industry as they pertain to the care and use of laboratory animals and animal research facilities and programs. The speakers will focus on issues such as sorting out collaborations, assuming responsibility: VA vs Academia, cost and benefits of industrial contracts and agreements; building a shared institutional animal care and use committee; proprietary information; and the regulatory agencies' perspective and oversight.

INQUIRIES

For further information concerning these workshops and future NIH Animal Welfare Education Workshops, contact:

Ms. Roberta Sonneborn
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-7163

NOTICES OF AVAILABILITY (RFPs AND RFAs)

RESOURCE CENTER ON HEALTH SERVICES RESEARCH

NIH GUIDE, Volume 23, Number 10, March 11, 1994

RFP AVAILABLE: N01DA-4-6203

P.T. 34; K.W. 0404009, 0730050

National Institute on Drug Abuse

The National Institute on Drug Abuse (NIDA) is soliciting proposals from qualified organizations that can provide a broad spectrum of health services research activities focused on the drug treatment system. The major objective of this request for proposals (RFP) is to obtain proposals for a multidisciplinary capacity to assemble system-wide information on applied health services research. Among the activities to be conducted are: developing an empirical knowledge base on the drug treatment system to support activities funded by NIDA; synthesizing existing drug related health services research studies; establishing a multidisciplinary capability to analyze health services research issues; conducting drug treatment related health services research and analyses; providing timely, comprehensive and research-based information on drug treatment services research; and establishing a discipline-balanced expert panel to integrate and review health service research to provide information on health services research strategies and directions. It is anticipated that a three-year incrementally funded contract with one twenty-four month option period will be awarded.

INQUIRIES

Estimated issuance date of RFP No. N01DA-4-6203 is March 8, 1994, and responses will be due 45 calendar days thereafter. This is a new procurement. Written requests for copies of solicitations will be honored if received within 35 calendar days after issuance of the solicitation. Written requests are to be forwarded to:

Ms. Carol Cushing
National Institute on Drug Abuse
Parklawn Building, Room 10-49
5600 Fishers Lane
Rockville, MD 20857
FAX: (301) 443-7595

CLINICAL/METABOLIC STUDIES IN NUTRITION AND BREAST CANCER PREVENTION

NIH GUIDE, Volume 23, Number 10, March 11, 1994

RFA AVAILABLE: CA-94-010

P.T. 34; K.W. 0715036, 0745027, 0710095, 0765020

National Cancer Institute

Letter of Intent Receipt Date: April 12, 1994
Application Receipt Date: June 9, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control, National Cancer Institute (NCI), invites Interactive Research Project Grants (IRPGs) (see NIH Guide, Vol. 22, No. 16, April 23, 1993), to encourage and facilitate formal interdisciplinary collaborations through the coordinated submission of related research project applications that share a common research focus relevant to the development and conduct of clinical/metabolic studies for nutrition and breast cancer prevention research and do not require extensive shared physical resources or core functions.

A minimum of two independent investigators with related research objectives will be encouraged to submit concurrent, collaborative, cross-referenced individual research project grant applications that share a common research focus.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Clinical/Metabolic Studies in Nutrition and Breast Cancer Prevention, is related to the priority area of cancer prevention. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-0043-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Domestic and foreign non-profit and for-profit organizations and institutions, governments and their agencies are eligible to apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions if appropriate. Applications from or involving minority institutions, individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be by the research project grant (R01). Applicants will be responsible for the planning, direction, and execution of the proposed projects. The total project period for applications submitted in response to the present RFA must not exceed four years.

This is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to customary peer review.

FUNDS AVAILABLE

Approximately \$2.5 million in total costs per year for up to four years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that six to nine awards will be made. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objectives of this RFA for Interactive Research Project Grants (IRPGs) are to (1) increase the investigator-initiated pool of quality applications employing clinical/metabolic studies in human nutrition and breast cancer research and (2) stimulate an intermediate level of interdisciplinary collaborative efforts to build stronger research bridges between nutritional science and the disciplines that relate closely to basic and clinical research for the development, application, and evaluation of new approaches to nutrition and breast cancer prevention research utilizing clinical/metabolic studies.

Research Areas of Interest

Representative areas of particular interest for this RFA focus on many basic issues of biological functions and modulating actions of dietary patterns and nutrients that need to be investigated directly in human studies. Another area of interest is the application of innovative research approaches to the development and evaluation of specific methodologies for use in human studies to elucidate the mechanisms of action and quantify the role of diet and dietary components in breast cancer prevention and control.

Several typical (non-exhaustive) examples of research areas relevant to the dietary intervention clinical/metabolic studies for nutrition and breast cancer prevention in which the IRPG concept may be applied are as follows:

- o Identification, evaluation, and validation of specific molecular, cellular, metabolic, and endocrine biomarkers that are associated with initiation and/or promotion of preneoplastic transformations that may be responsive to foods and nutrients
- o Determine the relation between dietary intake and gene expression in breast epithelial cells and breast cancer cells
- o Evaluate interactions such as nutrient-nutrient, nutrient-drug and genetic-environment interactions
- o Define dose-response relationships for macronutrients, micronutrients, and non-nutrient dietary constituents on molecular and cellular events and alterations in metabolic pathways
- o Characterize individual variability in the biological response to specific dietary patterns or nutrients
- o Identification of biochemical markers as quantitative measures of food intake, digestion, absorption, metabolic breakdown of specific nutrients, or nutritional status
- o Bioavailability of nutrients and non-nutrients at various intakes and from different food sources
- o Determine the relation between dietary intake of environmental carcinogens, i.e., pesticides and dioxins, and breast cancer, including potential effects of contaminants in the food and water supply

Prospective applicants are encouraged to explore other areas of potential for the IRPG mechanism with the NCI Program Director. The overall goal is to provide more definitive data for developing quantitative dietary guidance and translation into optimal and desirable eating patterns and food choices that have the potential for a substantial reduction in the risk of diet-related cancers in the general population.

Special Instructions for IRPG Applications

The NCI encourages qualified investigators to develop and submit concurrently coordinated research project applications that address areas of relevance to nutrition and cancer prevention where the interactive research project concept may be applied. Applications submitted as a package should be tightly focused and the interactions and benefits of the proposed linkages should be made explicit as described in the RFA. One Principal Investigator from the IRPG group MUST be identified as the "Program Coordinator," and should be cited in all applications on Page 2 of form PHS 398 (rev. 9/91). Individual investigators may request funds for the time and effort contributed toward the coordination of the overall research and for collaborative resource activities. Other required applicant information and special instructions for preparation of IRPG applications are also included in the RFA, which is available from the NCI Program Director listed under INQUIRIES.

All PHS and NIH grants policies will apply to applications received in response to this RFA.

STUDY POPULATIONS

SPECIAL INSTRUCTION FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 12, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is to be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
6130 Executive Boulevard
Executive Plaza North, Room 636
Rockville, MD 20852
Telephone: (301) 496-3428
FAX: (301) 402-0275

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892; and from the NCI Program Director listed under INQUIRIES.

Each application will be considered on its own merit as an individual research project. Therefore, applicants for IRPGs may not concurrently submit R01 applications that represent significant duplication of the efforts described in the applicant's IRPG. In this regard, it should be noted that the NCI will consider funding meritorious individual IRPG applications if it is not possible to fund the IRPG package as a whole. Concurrent submission of program project (P01) applications that request support for essentially similar work is prohibited.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed (initially) by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NCI program staff function. Questions concerning the responsiveness of proposed research to the RFA may be directed to the Program Director listed under INQUIRIES.

If the number of applications is large compared to the number of awards to be made, the NCI may conduct a preliminary scientific peer review to eliminate those applications that are clearly not competitive. The NCI will remove from competition those applications judged to be noncompetitive for award to notify the applicant and institutional business official. Those applications judged to be both competitive and responsive will be further evaluated according to the review criteria stated below for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by the National Cancer Advisory Board considers the special needs of the NCI and the priorities of the National Cancer Program.

AWARD CRITERIA

The anticipated date of award is March 1, 1995. Although this program is provided for in the financial plans of the National Cancer Institute (NCI), awards made pursuant to this RFA are contingent upon the availability of funds for this purpose. In addition to the scientific merit; priority score, availability of funds, and programmatic priorities will be considered in making awards.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquiries about whether or not specific proposed research would be responsive are encouraged. The program staff welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Carolyn K. Clifford, Ph.D.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Suite 212
Bethesda, MD 20892-6130
Telephone: (301) 496-8573
FAX: (301) 402-0553

Direct inquiries regarding fiscal matters to:

Kathleen Shino
Grants Administration Branch
National Cancer Institute
6120 Executive Boulevard
Executive Plaza South, Room 243
Rockville, MD 20852
Telephone: (301) 496-7800 Ext. 48

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399, Cancer Control. Awards will be made under the authority of the Public Health Services Act, Title IV, Section 301 (Public Law 78-410, 42 U.S.C. 241 and Section 412, as amended by Public Law 99-518, 42 U.S.C 258a-1); and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12732 or Health Systems Agency review.

RESEARCH ON TOPICAL MICROBICIDES FOR PREVENTION OF STDs/HIV

NIH GUIDE, Volume 23, Number 10, March 11, 1994

RFA AVAILABLE: AI-94-013

P.T. 34; K.W. 0715182, 0745027, 1002027, 0710070, 1002004

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: May 13, 1994

Application Receipt Date: July 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Sexually Transmitted Diseases Branch of the Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), invites research grant applications for program projects to conduct research necessary for the development of topical microbicides for intravaginal use to prevent sexually transmitted diseases (STDs), including Human Immunodeficiency Virus (HIV) infection. The NIAID wishes to expand research in this area through the conduct of multi-disciplinary research in microbiology, immunology, reproductive biology, reproductive toxicology, and cell biology. Basic and applied research that will lead to effective strategies for intravaginal protection against STDs, including HIV infection, are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Research on Topical Microbicides for Prevention of STDs/HIV, is related to the priority areas of sexually transmitted diseases and HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-10473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic, for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanism of support will be the Program Project grant (P01). Multidisciplinary approaches that involve collaborative efforts among investigators in microbiology, immunology, reproductive biology, reproductive toxicology, and cell biology specialties are strongly encouraged. The total project period for applications submitted in response to this RFA may not exceed four years.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for this RFA will be \$1.5 million. In fiscal year 1995, the NIAID plans to fund two program projects related to this RFA.

RESEARCH OBJECTIVES

A fundamental, common objective of the NIAID's STD/HIV research programs is to develop topical microbicides effective in preventing and controlling sexually transmitted infections. This requires focused multi-disciplinary research to develop safe, effective molecular strategies for blocking the early steps in the infectious process.

Scope of Research

Whereas it is recognized that safe, spermicidal-microbicides are important outcomes in the search for female-controlled barrier methods to prevent HIV infection and STDs, the development of spermicides that are not microbicidal is not an objective of NIAID.

Arguably the most productive approach to identifying safe, effective molecular strategies for blocking the early steps in the infectious process is based on multi-disciplinary efforts including, but not limited to, microbiology, immunology, reproductive biology, reproductive toxicology, and cell biology. Applicants are strongly encouraged to include microbiology and two additional disciplines in the program project.

A wide range of basic and applied research questions must be answered in order to meet this programmatic objective. Research issues and areas of high priority to the NIAID and to this RFA include, but are not limited to, the following:

Diseases of interest

Applicants are encouraged to address the following sexually transmitted diseases of high scientific priority to the NIAID:

- o HIV infection;
- o Chlamydial infection;
- o Gonorrhea;
- o Trichomoniasis;
- o Genital Ulcer Diseases, including syphilis, genital herpes (herpes simplex virus 1 and 2) and chancroid; and
- o Human papillomavirus infection.

Applicants are also encouraged to include the following areas of research:

- o Early steps in infectious processes
- o Microbicide evaluation
- o Biology of the reproductive tract
- o Reproductive toxicology

The goal, as envisioned, is to develop topical microbicides with activity against a combination of pathogens including viral, bacterial and protozoan. For this reason, research on two sexually transmitted diseases, preferably one viral and one bacterial, is highly recommended.

Projects may involve collaboration among investigators at several institutions. Consortium arrangements should follow "Guidelines for Establishing and Operating Consortium Grants, January 1989", available from the individuals listed under INQUIRIES.

Project Leaders and Program Directors should budget for an annual one day progress review meeting at a site to be designated (either in Bethesda or in association with a relevant national meeting).

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a special justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 13, 1994, a letter of intent that includes a descriptive title of the overall proposed research program and the name, address and telephone number of the Principal Investigator; a descriptive title of each of the projects and the names of the proposed project leaders and other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted. The letter of intent should be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), the standard application form for research grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applicants must adhere to the format and requirements specified in the PHS 398 application kit.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID for responsiveness to this RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration. Those considered complete and responsive may be subjected to a triage review by an NIAID peer review group to determine their scientific merit relative to the other applications. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee. A second level of review will be provided by the NIAID Advisory Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone requests for this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Requests for the RFA, as well as inquiries regarding programmatic issues may be directed to:

Dr. Penelope J. Hitchcock
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A-21
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-0443
FAX: (301) 402-1456
Email: penny@exec.niaid.pc.niaid.nih.gov

Direct inquiries regarding review issues and address the letter of intent to:

Olivia Preble, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C19
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Sharie Bernard
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B32
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

| | |
|--------------------------------|---------------|
| Letter of Intent Receipt Date: | May 13, 1994 |
| Application Receipt Date: | July 13, 1994 |
| Scientific Review Date: | October 1994 |
| Advisory Council Date: | February 1995 |
| Earliest Date of Award: | April 1995 |

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.856 - Microbiology & Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

GENETIC DETERMINANTS OF HIGH BLOOD PRESSURE

NIH GUIDE, Volume 23, Number 10, March 11, 1994

RFA AVAILABLE: HL-94-011

P.T. 34; K.W. 1002019, 0715115

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: June 17, 1994

Application Receipt Date: September 16, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The objective of this RFA is to establish: (1) Genetic Networks of collaborating investigators to exploit modern molecular genetic tools to map and identify the major genetic determinants of high blood pressure, and (2) Genetic Epidemiology Networks that, in addition to gene mapping and identification described above, will also study interactions between genetic and non-genetic determinants of hypertension in defined populations.

A network will pursue the requisite tasks, provide the essential tools and infrastructure, link the best people and resources in several locations, and provide essential cohesion and coordination among its component parts. Each network will be fully capable of pursuing all necessary facets required to map and identify genetic factors responsible for high blood pressure, including recruitment, phenotyping, genotyping, and data management and analysis. These tasks can be organized according to a variety of schemes and rationales to form a network, as long as all requisite activities essential to achieving the objectives of this RFA are included. For example, these network activities could be organized into the following components: Field Centers, Laboratory Center, Genotyping Center, Data Coordinating Center, and Animal Mapping Center. Each component of a network will be directed by a principal investigator and will receive a separate award.

Multi-network Activities

Although each network funded by this program may differ in strategies, design, and methodology, there will be numerous beneficial and exciting opportunities for collaboration among the different networks that will expedite and enhance the specific aims of each network and the overall objectives of this RFA. Consequently, a Program Steering Committee will be used to facilitate the establishment and conduct of multi-network activities, such as develop and initiate collaborative studies, develop uniform protocols, standardize methods, share data and resources, generate new ideas and strategies that result from new research findings, and ensure a minimum of research and budgetary duplication. Those aspects of a network that do not involve sharing and collaboration between networks may be pursued independently by that network.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Genetic Determinants of High Blood Pressure, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. However, under exceptional circumstances, a foreign component that is critical to the success of the network and minor in its magnitude, may be included as part of a domestic application. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative clinical research agreement (U10), an "assistance" mechanism, in which substantial National Institutes of Health (NIH) scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Further details are in the complete RFA.

FUNDS AVAILABLE

Up to four networks may be funded under this RFA, depending upon availability of funds for this purpose. A network will be comprised of components. Each component will be directed by a Principal Investigator and will receive a separate award. As network tasks can be organized according to a number of different organizational strategies, each network could be comprised of four to seven components (awards). Hence, if four networks are funded, the total number of awards might vary from 12 to 28.

A maximum of about \$30 million (including direct and indirect costs) over a five-year period will be awarded. Approximately \$4.50 million may be available for the first year, \$6.00 million for the second year, \$6.24 million for the third year, \$6.50 million the fourth year and \$6.76 million for the last year.

RESEARCH OBJECTIVES

Background

Hypertension, a complex disease that involves the interplay of genetic and environmental factors, affects an estimated 50 million Americans and is a major predisposing factor for myocardial infarction, vascular disease, stroke, and renal failure. It has been estimated from segregation analysis and twin studies that approximately 45 percent of the interindividual differences in blood pressure are accounted for by genetic differences. The identification of the genes whose variants contribute to high blood pressure will have far-reaching effects on our understanding of the pathophysiology of the circulation and may suggest new preventive measures and rational therapeutic approaches.

Until recently, the techniques for dissecting the genetic determinants of high blood pressure were not available or were not developed to an extent that would make the proposed project feasible. Several recent advances in technology and analytical methods, together with the rapid construction of genetic maps, have substantially improved the chances of detecting these genetic factors.

Objectives and Scope

The goal is to identify the genes involved in hypertension by using an alliance of talented investigators skilled in the appropriate scientific disciplines who will use the most sophisticated and modern molecular genetic approaches. In addition to gene mapping and identification, investigators may also apply to study interactions between genetic and non-genetic determinants of hypertension in defined populations. Consequently, support will be provided to collect and characterize appropriate family configurations, to phenotypically and genotypically characterize members of these configurations, and to perform genetic and statistical analyses to localize and identify genetic factors responsible for high blood pressure. Studies utilizing genetic inbred animal models (especially rats) may also be included under special circumstances, as presented in the RFA.

Study Design, Methodology, and Analysis

There are a number of feasible study designs that could achieve the objectives of this program, depending upon the varying degrees of certainty regarding the true modes of inheritance, the understanding of underlying physiology of disease processes, and the availability of appropriate intermediate phenotypes. Therefore, the exact study design(s), methodology, and analytical tools employed may differ among networks. Regardless of the particular strategy chosen, it is absolutely critical for the applicants to carefully justify the methodology, strengths, and limitations of the study design, analytical strategies, statistical tools, and the selection of the population.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, the NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 17, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Network Director, the identities of other key personnel and participating institutions, and the number and title of this RFA.

A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. The information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the selection of reviewers.

The letter of intent is to be sent to:

C. James Scheirer, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557
Bethesda, MD 20892
Telephone: (301) 594-7478
FAX: (301) 402-1660

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIH Project Scientist listed under INQUIRIES. Investigators who wish to establish a network will submit concurrent, cross-referenced individual research grant applications together as a package. Refer to the RFA for more detailed instructions.

REVIEW CONSIDERATIONS

Major factors to be considered in the evaluation of applications include the scientific and technical merit of the proposed research; the qualifications, experience, and level of commitment of the key investigators; plans for coordination, cooperation, and sharing of biological and informational resources, both within a network and across networks; the strategy to meet all special requirements, terms, conditions, and specifications stipulated in the complete RFA; the adequacy of the environment and facilities; and the appropriateness of the budget.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Stephen C. Mockrin, Ph.D.
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 4C10
Bethesda, MD 20892
Telephone: (301) 496-1613
FAX: (301) 402-2044
EMAIL: SM60D@NIH.GOV

Direct inquiries regarding fiscal and administrative matters to:

Ms. Jane Davis
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 594-7436
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This project is described in the Catalog of Federal Domestic Assistance No. 93.837. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR 74. This project is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

GENOME SCIENCE AND TECHNOLOGY CENTERS

NIH GUIDE, Volume 23, Number 10, March 11, 1994

PAR AVAILABLE: PAR-94-044

P.T. 34; K.W. 1215018, 0755045

National Center for Human Genome Research

THIS IS A NOTICE OF AVAILABILITY OF A PROGRAM ANNOUNCEMENT (PA). IT IS ONLY AN ABSTRACT OF THE PA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE PA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE PA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The purpose of this program announcement is to solicit new or renewal applications to the Genome Science and Technology Centers (GESTEC) program, which supports large-scale, multidisciplinary genomic studies designed to achieve the mapping and sequencing goals of the Human Genome Project as set forth in the New Five-Year Plan for the U.S. Human Genome Project (Science, Vol. 262, p. 43, October 1, 1993). The GESTEC program is intended to foster and support innovative projects in which technology development, data throughput, and cost-effectiveness are expected to push the limits of current capabilities. The GESTEC program is NOT intended to fund projects in which existing technology is simply applied to large-scale data production or projects that involve a consortium of investigators whose research interests are only loosely united by a common theme.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. While a single institution must be the applicant, multi-institutional arrangements (consortia) are possible if there is a compelling reason for them and if there is clear evidence of close interaction among the participants. Applications from foreign institutions will not be accepted. However, subcontracts to foreign institutions are allowable, with sufficient justification. Applications from minority individuals and women are encouraged. Industrial/academic collaborations are also encouraged.

MECHANISM OF SUPPORT

Grants in the GESTEC program may be supported by specialized center grants (P50) or program project grants (P01). The P50 mechanism will be used for broader, more complex, multidisciplinary programs that address the goals of the Human Genome Project. The P01 mechanism will be used for programs that support a minimum of three components with a well-defined central research focus. The term of support for GESTEC projects is normally three to five years.

RESEARCH OBJECTIVES

The National Institutes of Health (NIH) is currently engaged, along with several other federal, private, and international organizations, in a 15-year research program designed to characterize the human genome and the genomes of selected model organisms. The product of the Human Genome Project will be a set of information and material resources available to the entire research community that will facilitate further research leading to the prevention, diagnosis, and therapy of disease, as well as a further understanding of human biology.

The NCHGR and DOE recently published the above-referenced new five-year plan extending the initial goals for the U.S. Human Genome Project. At the same time, the NCHGR has established a reformulated centers program, the Genome Science and Technology Centers (GESTEC) program. This announcement solicits applications for new and continuing research that proposes to address the needs outlined in the new five-year plan, leading toward complete sequencing of the human genome and the genomes of selected model organisms.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Although it is not required or binding, applicants are strongly urged to contact NCHGR staff by telephone or by letter of intent. This will enable staff to provide clarification of programmatic and budgetary issues regarding these often-complicated applications and will also assist review staff in planning the review workload.

This communication will be most useful if it is submitted at least three months before the receipt date on which the application is to be submitted. It need include only the names of the principal investigator and principal collaborators, a descriptive title of the proposed application and identification of the organization(s) involved. This information will not be part of the material that will be peer reviewed and should be directed to the NCHGR program staff listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the application deadlines as indicated in the application kit. Application kits are available from most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application. The completed original and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Additionally, two copies of the full application must be sent to:

Office of Scientific Review
National Center for Human Genome Research
Building 38A, Room 604
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by DRG staff for completeness and, for those applications assigned to the NCHGR, by NCHGR staff for appropriateness with respect to expressed NCHGR programmatic interests. Incomplete or inappropriate applications will be returned to the applicant without further consideration.

The regular NIH receipt dates for center grant and program project applications and renewals are as follows: February 1, June 1, and October 1. Applications will be evaluated for scientific merit by the Genome Research Review Committee (GRRRC) or an appropriate review committee constituted for the purpose of evaluating GESTEC grant applications. Site visits are frequently conducted as part of the review process, but are not routine. Therefore, applicants should present a complete and well-justified written proposal and not depend on a site visit to amplify the application.

Review criteria will include the following: (1) significance and originality of the research and methodological approaches; (2) feasibility of the research and adequacy of the experimental design; (3) training, experience, research competence and commitment of the investigator(s); (4) adequacy of the facilities and resources; and (5) provisions for the protection of human subjects, the humane care of animals and biosafety conditions.

Subsequent to evaluation by the initial review group, applications will be reviewed by the appropriate National Advisory Council or Board.

AWARD CRITERIA

For applications assigned to the NCHGR, the following will be considered in making funding decisions: (1) quality of the proposed project as determined by peer review; (2) value of the proposed research and of the proposed technology development for achieving the goals of the Human Genome Project; (3) adequacy of the proposed management structure; (4)

nature and extent of the outreach program, including the adequacy of any plans proposed for sharing and distributing data and resources in a timely manner; (5) balance among projects within the NCHGR's grant portfolio; and (6) availability of funds.

INQUIRIES

Written and telephone inquiries are strongly encouraged. The program announcement and GESTEC grant application guidelines should be requested before preparing the grant application. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding the GESTEC program may be directed to:

Jane L. Peterson, Ph.D.
Mammalian Genomics Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
Internet: Jane_Peterson@occhost.nlm.nih.gov

Inquiries regarding fiscal matters may be directed to:

Ms. Jean Cahill
Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NEW AND IMPROVED TECHNOLOGIES FOR GENOMIC RESEARCH AND ANALYSIS

NIH GUIDE, Volume 23, Number 10, March 11, 1994

PA AVAILABLE: PA-94-045

P.T. 34; K.W. 1215018, 0755045

National Center for Human Genome Research

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PURPOSE

[This program announcement supersedes the previous announcement that was published in the NIH Guide to Grants and Contracts, Vol. 21, No. 9, Part 2 of 2 parts, March 6, 1992.]

The National Center for Human Genome Research (NCHGR) invites applications to support research that will significantly advance progress toward achieving the extended scientific goals of the Human Genome Program (HGP). These goals are described in the article, "A New Five-Year Plan for the U.S. Human Genome Project" (*Science*, vol. 262, p. 43-46), which covers the years 1994-1998. Because of the need to increase the rate and efficiency and to lower the cost of mapping and sequencing, the main focus of this program announcement is to solicit projects directed to the development of new or the significant improvement of current methods, strategies and technologies for mapping, sequencing, informatics and gene identification.

ELIGIBILITY REQUIREMENTS

Domestic and foreign universities, medical colleges, hospitals, corporations, and other public, private, or for-profit research institutions, including state and local government units, are eligible. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minorities, women, and individuals with disabilities are especially encouraged.

MECHANISM OF SUPPORT

Support for this program will be through research grants, including research project grants (R01) and FIRST (R29) awards.

RESEARCH OBJECTIVES

Research projects in the following areas are encouraged:

- o Technologies for improving physical maps;
- o Advanced DNA sequencing technologies;

NIH Guide for Grants and Contracts - Vol. 23, No. 10 - March 11, 1994

- o Technologies for refining genetic linkage maps, development of methods for rapid genotyping, and the development of new, easier-to-use genetic markers;
- o New technologies for gene identification; and
- o Informatics, including the development and improvement of appropriate computer tools and information systems for the collection, storage, retrieval and distribution of mapping and sequencing data, as well as the development of new methods and tools for the analysis and interpretation of genome maps and DNA sequences.

Initially, the mapping and sequencing of the genomes of *E. coli*, *S. cerevisiae*, *C. elegans*, *D. melanogaster*, and the laboratory mouse were taken as goals of the U.S. HGP. Applicants may also propose to study model systems other than those listed. The choice of organism, however, must be justified as contributing significantly to achieving the overall objectives of the HGP, must have technology development as the primary focus, and must be applicable to the analysis of the human genome.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Submission dates for new applications are February 1, June 1, and October 1; competing continuation applications and amended applications are accepted on March 1, July 1, and November 1. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

The completed original application and five legible copies must be delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will first be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Following the initial scientific review, applications will receive a second-level review by the appropriate National Advisory Council or Board.

Review criteria that will be used to assess the scientific merit of an application are: (1) Significance and originality of the research and methodological approaches; (2) Feasibility of the research and adequacy of the experimental design; (3) Training, experience, research competence, and commitment of the investigator(s); (4) Adequacy of the facilities and resources; and (5) Appropriateness of the requested budget for the work proposed.

AWARD CRITERIA

Applications assigned to the NCHGR will compete for available funds with all other approved applications assigned to the NCHGR. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review and potential for developing technology or strategies that will accelerate progress in mapping and sequencing the human genome;
- o Value of the proposed research for achieving the research goals of the NCHGR, while maintaining programmatic balance in the NCHGR grant portfolio;
- o Adequacy of any plans proposed for managing data and sharing data, resources and technology in a timely manner; and
- o Availability of funds.

In addition to the above award criteria, applications from foreign institutions must present special opportunities for research accomplishments that are not readily available in the United States.

INQUIRIES

Written, telephone, and electronic requests for the complete program announcement and the opportunity to clarify any issues on questions from potential applicants are welcomed.

Direct requests for the program announcement and inquiries regarding programmatic issues to:

Bettie J. Graham, Ph.D.
Mapping Technology Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
Internet: Bettie_Graham@occhost.nlm.nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Jean Cahill
Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or to Health Systems Agency review.

PILOT PROJECTS OR FEASIBILITY STUDIES FOR GENOMIC ANALYSIS

NIH GUIDE, Volume 23, Number 10, March 11, 1994

PAR NUMBER: PAR-94-046

P.T. 34; K.W. 1215018, 0755045

National Center for Human Genome Research

PURPOSE

[This program announcement supersedes the previous announcement that was published in the NIH Guide for Grants and Contracts, Vol. 19, No. 28, July 27, 1990.]

The National Center for Human Genome Research (NCHGR) invites applications for pilot projects/feasibility studies that have the potential for significantly advancing progress toward achieving the extended scientific goals of the Human Genome Program as recently described in Science. Vol. 262, 43-46, 1993. The purpose of this program announcement is to encourage applications from individuals who are interested in developing novel, creative approaches that will provide significant advances in the areas of physical map annotation, DNA sequencing, high-throughput genotyping, gene identification and informatics, but which are not yet fully developed enough to successfully compete for a standard R01 grant.

ELIGIBILITY REQUIREMENTS

Domestic universities, medical colleges, hospitals, corporations, and other public, private, or for-profit research institutions, including state and local government units, are eligible. Applications from minorities, women, and individuals with disabilities are especially encouraged.

MECHANISM OF SUPPORT

This program will be supported through the exploratory/developmental grants (R21) mechanism. Applicants may request up to two years of support. Projects will be limited to \$100,000 (direct cost per annum). These grants will not be renewable; continuation of projects developed under this program will be through the research grant program.

RESEARCH OBJECTIVES

Background

The National Institutes of Health (NIH) is currently engaged, along with several other federal, private, and international organizations, in a 15-year research program designed to characterize the human genome and the genomes of selected model organisms. This research program, the Human Genome Project (HGP), has the following interrelated goals:

- (1) the construction of high-resolution genetic linkage maps;
- (2) the development of detailed physical maps;
- (3) the determination of the complete nucleotide sequence of the human genome and the genome of selected organisms;
- (4) the development of efficient methods of identifying genes and for placement of known genes on physical maps or sequenced DNA;
- (5) the development of the capability to collect, store, distribute and analyze the data and materials produced;
- (6) the development of appropriate new technologies to achieve these goals; and
- (7) the identification of major issues related to the ethical, legal and social implications (ELSI) of genome research, and the development of policy options to address them.

The products of the HGP will include information and material resources, as well as new technologies, available to the entire research community that will facilitate further research leading to the prevention, diagnosis, and therapy of disease, as well as to further understanding of human biology.

Significant progress has been made toward meeting the initial five-year goals of the HGP (as described in the document "Understanding Our Genetic Inheritance - The U.S. Human Genome Project: The First Five Years FY 1991-1995). Meeting the set of extended goals of the HGP and completing the HGP, however, will require still further increases in efficiency and cost-effectiveness of mapping and sequencing techniques. Achieving such increases will undoubtedly benefit from the development of new approaches. Pilot projects can be a valuable means of promoting the development of novel or conceptually creative ideas that are scientifically sound and may significantly advance progress toward the scientific goals of the Human Genome Program, but which may not be developed fully enough to warrant support with a standard R01 grant.

Objectives

Applications for pilot projects or feasibility studies are encouraged in, but not limited to, the following areas:

- o development of new technologies for improving STS-based physical maps at a resolution of 100 kilobases;
- o development of new methods for DNA sequencing that are capable of significantly reducing the cost and/or increasing the throughput of sequencing;
- o development of high-throughput genotyping technologies that are accurate, rapid, efficient and cost-effective;
- o development of new technologies for rapidly and cost-effectively identifying and mapping genes and coding regions in genomic DNA;
- o development of computer tools, information systems, and strategies for collecting, storing, retrieving, analyzing, interpreting and distributing large amounts of mapping and sequencing data.

The purpose of this initiative is to identify high-risk/high payoff projects that, if successful, could lead to significant increases in the rate of data generation, significant decreases in the cost of genomic research, or significant new insights. The NCHGR encourages applications from scientists who have not traditionally been funded by the NCHGR, such as chemists, engineers, physicists, and information scientists, as well as from molecular biologists and other biologists.

Applicants must clearly identify the biological problem for which the technology is being developed, and must indicate plans for demonstrating or testing the utility of the technology. Applicants whose expertise is primarily non-biological and who are interested in addressing problems of genome analysis with new, non-biological tools are especially encouraged to interact closely with biologists.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Submission dates for new applications are February 1, June 1, and October 1; competing continuation applications and amended applications are accepted on March 1, July 1, and November 1. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Item 2a on the face page of the application.

The completed original application and five legible copies must be delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will first be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Following the initial scientific review, applications will receive a second-level review by the National Advisory Council for Human Genome research. The following review criteria will be used to assess the scientific merit of an application:

- o Significance and originality of the research and methodological approaches;
- o Feasibility of the research and adequacy of the experimental design;
- o Training, experience, research competence, and commitment of the investigator(s);
- o Adequacy of the facilities and resources; and
- o Appropriateness of the requested budget for the work proposed.

Because this program is designed to support innovative ideas, preliminary data are not required. However, the applicant does have the responsibility for developing a sound research plan and for presenting any other information that can be considered as evidence of feasibility.

AWARD CRITERIA

Applications assigned to the NCHGR will compete for available funds with all other approved applications assigned to the NCHGR. The following will be considered in making funding decisions:

- o Innovativeness of the proposed project as determined by peer review;
- o The potential for developing technology or strategies that will accelerate progress toward achieving the research goals of the National Center for Human Genome Research; and
- o Availability of funds.

INQUIRIES

The program staff and grants management officer welcome the opportunity to discuss program interests and PHS grant policy, respectively, with prospective applicants and current grantees. Telephone, electronic and/or written inquiries are strongly encouraged. Specific questions regarding programmatic areas may be directed to:

Bettie J. Graham, Ph.D.
Mapping Technology Branch
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
Internet: Bettie_Graham@occhost.nlm.nih.gov

Inquiries about fiscal matters may be directed to:

Ms. Jean Cahill
Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or to Health Systems Agency review.

DRUG ABUSE HEALTH SERVICES RESEARCH

NIH GUIDE, Volume 23, Number 10, March 11, 1994

PA NUMBER: PA-94-047

P.T. 34; K.W. 0404009, 0730050

National Institute on Drug Abuse

PURPOSE

The purpose of this Program Announcement is to encourage applications for a new program emphasis on health services research in the field of drug abuse.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Drug Abuse Health Services Research, is related to the priority area of alcohol and other drugs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit public and private organizations such as universities, colleges, hospitals, units of State or local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

This program announcement will use the National Institutes of Health (NIH) individual research grant (R01), interactive research project grant (IRPG) (see NIH Guide, Vol 22, No. 16, April 23, 1993), small grant (R03), and FIRST award (R29). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Support will be provided for a period of up to five years (renewable for subsequent periods) subject to continued availability of funds and progress achieved.

RESEARCH OBJECTIVES

The ADAMHA Reorganization Act (Public Law 102-321) directed the National Institute on Drug Abuse (NIDA) to expand its program of health services research. Health services research is defined as research endeavors that study the organization, financing, and management of health services and their impact on the quality, cost, access to, and outcomes of care (Section 409). Subsequent legislative clarification included research to study the effectiveness of primary and secondary prevention activities. Research on the efficacy of services to prevent, diagnose, or treat medical conditions is excluded (Public Law 103-43), and investigators contemplating such studies should consult other relevant NIDA announcements.

NIDA's health services research program includes interdisciplinary study of the structure, processes, and outcomes of the delivery of health services. Factors that influence the availability, accessibility, and utilization of health services and the efficiency and effectiveness of these services are studied within established service delivery settings and at a system-wide level. Research is sought on how services are organized, financed, delivered, and utilized as well as how effective these services are in addressing health issues and related concerns.

This Program Announcement invites research grant applications in four major areas of health services research: (1) primary and secondary prevention activities; (2) HIV prevention services for drug abusers and their sexual partners, both in and out of health care settings; (3) health services for drug abusers in primary care settings, and linkages between primary care and drug abuse treatment programs/systems; and (4) drug abuse treatment services research at system, program, and client levels.

Illustrative general or cross-cutting health services research areas include:

- o Assessment of need for services and factors influencing utilization of services;
- o Effectiveness and efficiency of alternative organizational and manpower configurations;
- o Client/patient, provider, and community/environmental characteristics that affect service delivery and outcome;
- o Financing and economic research on programs, practices, policies, and outcomes;
- o Assessment, matching and referral of patients to improve services and outcomes;
- o Impact of specific policies or cost/utilization control strategies on outreach, service delivery, retention, and effectiveness; and
- o Methodological development in research designs, analytic techniques, and measurement, including development of standards and criteria.

Applications that focus on research within any of the four major areas or that cut across areas are encouraged. Topics not mentioned are not necessarily excluded from consideration under this Program Announcement.

Applicants are advised to review existing information relevant to drug abuse health services research and to design studies using the most rigorous methodological and analytic designs feasible. Timely reporting of findings is emphasized. Applicants should be willing to participate in research coordination efforts to maximize the utility of the research, including review and dissemination activities.

If investigators are studying populations that are at risk for HIV, they are encouraged to explicitly address AIDS-related issues in their applications. Investigators are encouraged to offer HIV testing and counseling in accordance with current guidelines to subjects identified during the course of the research as being at risk for HIV acquisition or transmission. In high-risk populations, investigators are encouraged to assess the effects of new interventions on the acquisition and transmission of infectious diseases, including HIV. Due to the growing AIDS problem in this country, special consideration will be given to applications that focus on AIDS-related issues such as services to reduce AIDS risk behaviors, services for high-risk subgroups such as prostitutes or injection drug users, or measures of program effect on AIDS risk behaviors (e.g., needle sharing, unprotected sex).

Drug Abuse Prevention. The intent of health services prevention research is to assess the effectiveness and cost effectiveness of preventive interventions in reducing drug-related problems. Research is needed to improve the quality of prevention services, to expand access to prevention services to all populations, particularly minorities, and to lower costs of health care by reducing the extent of drug use and its adverse medical, psychological, and social consequences.

In addition to intervention studies in health care settings, prevention services research may occur in a variety of other settings (e.g., worksites, schools, and local communities) and may focus on financing, organization, management, enforcement, and utilization of prevention services as well as their effectiveness.

Illustrative drug abuse prevention services research areas include:

- o Qualitative and quantitative assessment of the impact of program service delivery at the community, State, regional, or national level;
- o Outreach research to assess strategies to expand prevention services to underserved populations and geographic areas, such as rural communities and inner cities;
- o Research on methods for diffusion of innovative clinical practices and management techniques to improve prevention services and lower costs;
- o Research on consumer choice, prevention program selection, and service retention resulting from innovative practices; and
- o Research to integrate drug abuse prevention with interventions directed at other related behavioral and societal problems such as violence, unwed pregnancy, school dropouts, and domestic abuse.

HIV Prevention. Behavior change remains the only strategy available to prevent HIV infection. To date, research has focused on the implementation and testing of interventions designed to reduce drug-using and sexual behaviors that place the individual at high risk for HIV infection or transmission. Little research attention has been given to the need, demand, utilization, effectiveness, and cost effectiveness of HIV prevention and outreach in various settings and with specific subgroups. Further research is needed to develop and refine service delivery models for outreach to the population at risk of HIV infection.

Results of community-based research indicate that over 40 percent of injecting drug users contacted, including many long-term users of illicit drugs, have never enrolled in drug abuse treatment. Given the threat of HIV/AIDS to drug abusers and their sexual partners, research is needed to develop and refine risk reduction intervention strategies and methods of referral to medical and drug treatment to intervene with these high-risk populations.

Illustrative HIV prevention services research areas include:

- o Improving the effectiveness and cost effectiveness of HIV outreach and prevention services on reducing risk behaviors;
- o Delivery of HIV prevention and outreach services in nontraditional settings (e.g., in the community; in criminal justice settings), and barriers to delivery;
- o Delivery of HIV prevention interventions to non-treatment as well as treatment populations and for specific subgroups at risk, including criminal justice-involved, HIV+, adolescent, and those with chronic medical conditions (e.g., tuberculosis) or psychiatric problems;
- o Improving identification, liaison, and linkages with external resources, and managing information and access to service networks;

- o Development of valid and reliable measures of high-risk behaviors, of behavior change, of alternative HIV antibody testing and reporting strategies, and of measures to assess client need and match services to need.

Primary Care for Drug Abusers. Individuals dependent upon illicit drugs often have limited access to primary medical care, resulting in overuse of expensive emergency treatment. The social costs of drug abuse are multiplied by poor rates of compliance with treatment for tuberculosis and other diseases.

Health services research in primary care is needed to determine the effects of organizational and financing arrangements on access to primary care, on research to improve primary care/drug abuse treatment linkages, and to provide training opportunities for prevention, treatment, and primary care providers.

Illustrative research areas in primary care for drug abusers include:

- o Health services research on programs combining drug abuse and primary care, including cross-training for primary care providers and drug abuse treatment providers;

- o Studies to improve how health care and other organizations receive, assimilate, and adopt or respond to knowledge (e.g., new treatment strategies; clinical records information) bearing on treatment of drug abusers;

- o Studies to enhance early identification of drug abuse and associated medical problems (e.g., HIV infection and its consequences, tuberculosis, hepatitis B, sexually transmitted diseases) in non-drug abuse treatment settings, such as STD clinics or educational settings; and

- o Research to enhance client/patient engagement in and compliance with medical treatment programs.

Drug Abuse Treatment. Research is needed on treatment services and service delivery systems, on the influence of financing and health care coverage, and on the impact of these factors upon treatment outcomes. In the context of limited treatment resources, a need exists to determine the relative costs and benefits of providing augmented treatment services or improving drug abuse treatment service delivery systems.

The intent of treatment services research is to assess the impact of health services and the effects of organizational and financing arrangements on the quality and outcomes of care provided to patients with drug abuse as well as medical and other problems related to drug abuse.

Illustrative drug abuse treatment services research areas include:

- o Effects of financing, reimbursement, regulatory strategies, and insurance strategies, including the impact of differences in public and private financing and coverage, on access, quality, outcomes of care, and subsequent utilization of health care services;

- o Long-term aspects of drug abuse treatment utilization and recovery processes;

- o Client and program factors that influence treatment-seeking behavior, retention, compliance, effectiveness, and relapse, including program factors that influence change in AIDS risk behaviors, and factors related to engaging and retaining HIV+ drug users in treatment; and

- o Facility- or system-level studies to investigate the organization, management, financing, and quality of treatment and ancillary services in relation to client characteristics, treatment content, and outcome.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objective of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of the United States racial/ethnic minority populations (i.e., American Indian or Alaskan Natives, Asians or Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study

broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301-594-7248. The title and number of the announcement must be typed in Item 2a on the face page of the application.

FIRST award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original and five permanent, legible copies of the PHS 398 form must be delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary DHHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established PHS referral guidelines. The IRGs, consisting primarily of non-federal scientific and technical experts, will review the applications for scientific and technical merit in accordance with the standard NIH peer review procedures. Notification of the review recommendations will be sent to the applicant after the initial review. Applications recommended for further consideration will receive a second-level review by an appropriate Advisory Council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for further consideration by the Council may be considered for funding. Small grant (R03) applications do not receive a second level review.

AWARD CRITERIA

Applications recommended for further consideration by a National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the application as determined by peer review, appropriateness of budget estimates, program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds. Special consideration will be given to applications that directly deal with AIDS-related issues.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Frank M. Tims, Ph.D.
Treatment Services Research Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-30
Rockville, MD 20857
Telephone: (301) 443-4060

Direct inquiries regarding fiscal matters to:

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of the Public Health Service Act, Section 301, and administered under PHS policies and Federal Regulations at Title 42 CFR 52 "Grants for Research Projects," Title 45 CFR Part 74 & 92, "Administration of Grants" and 45 CFR Part 46, "Protection of Human Subjects." Title 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SMALL GRANTS FOR THERAPEUTIC CLINICAL TRIALS OF MALIGNANCIES

NIH GUIDE, Volume 23, Number 10, March 11, 1994

PAR NUMBER: PAR-94-048

P.T. 34; K.W. 0745005, 0745062, 0785210

National Cancer Institute

Application Receipt Dates: June 1, October 1, February 1

PURPOSE

The Division of Cancer Treatment (DCT), National Cancer Institute (NCI) announces a program to encourage the submission of small grant applications for new pilot, phase I, or phase II therapeutic clinical trials of malignancies that take advantage of recent laboratory developments. New and experienced investigators in relevant fields and disciplines (clinical, surgical, and radiation oncology) may apply for small grants to test new treatment strategies or do pilot studies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Small Grants for Therapeutic Clinical Trials, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications may be from a single institution or several institutions (collaborating institutions, consortia, clinical trials cooperative groups), if appropriate. New and experienced investigators are encouraged to apply. Applications from minority and women individuals encouraged.

MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) small grants (R03) mechanism. The small grants research program provides limited funds (maximum of \$50,000 direct costs per year) for short-term (up to two years) research projects. These grants are non-renewable and continuation of projects developed under this program will be through the regular grant program.

Applicants will be responsible for the planning, direction, and execution of the proposed project. Applications submitted in response to this Program Announcement (PA) will compete for funds with all other R03 grant applications assigned to the NCI. The award of grants in response to this PA is also contingent upon the availability of funds. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

RESEARCH OBJECTIVES

Background

The NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants, and cooperative agreements. At present, there is no mechanism targeted to stimulate the communication of promising and potentially relevant new developments between the laboratory and the clinical setting. There is a need for a mechanism to fund short-term studies and obtain preliminary clinical data rapidly. It is expected that these R03 grants will serve as a basis for planning future clinical research grant applications (R01) or NCI cooperative clinical trial group studies.

The small grants (R03) mechanism provides research support specifically limited in time and amount for studies in categorical program areas (see Research Goals and Scope). Small grants provide flexibility for initiating preliminary, short-term studies and are non-renewable. Furthermore, the time interval from application to funding is shortened under the R03 mechanism, thus allowing new ideas to be investigated or pursued in a more expeditious manner. The Cancer Therapy Evaluation Program, DCT, NCI has targeted the use of the small grants mechanism to support single or several institutions to perform therapeutic clinical trials to test new ideas. Support is needed to encourage new as well as experienced investigators to apply new treatment approaches.

Research Goals and Scope

The aim of this initiative is to support pilot, phase I, or phase II therapeutic clinical trials of malignancies to move new treatment strategies more rapidly from the laboratory into the clinic. Clinical studies must involve human subjects and be therapeutic in design. The clinical studies must be based on a strong rationale and preclinical data should support the underlying hypotheses. The research plan should be focused on the clinical trial proposed. New clinical therapeutic trials employing drugs, biologics, radiation, or surgery whether used as a single agent/modality or in combination are appropriate.

Laboratory studies may also be proposed to conduct pharmacokinetic, pharmacodynamic, and other important correlative studies in the cancer patients receiving therapy. The laboratory studies should be in support of the clinical trial, such that their conduct leads to a greater understanding of the relationship between drug administration and biological changes in patients.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

NIH policy is that applicants for NIH clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign consortium participants, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Applications must be received by the following receipt dates: June 1, October 1, and February 1 of 1994 and 1995. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this Program Announcement must be typed in line 2a on the face page of the application.

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, one additional copy of the application must also be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636A
6130 Executive Boulevard
Bethesda, MD 20892

The application must meet the requirements listed below.

The Research Plan of the application is limited to 16 pages total. A suggested page limitation is as follows:

- o Specific Aims - one page
- o Background, Significance, and Preliminary Studies - five pages
- o Research Design and Methods - 10 pages

Following the research plan, include the discussion of Human Subjects and the literature cited. Human subjects approval and IRB approval of clinical protocols must be obtained prior to review. Documentation for the composition of the proposed study population in terms of gender and racial/ethnic group together with a rationale for its choice must be included in the Human Subjects section. The clinical protocol must be included in the Appendix.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by an appropriate review group at the Division of Extramural Activities, National Cancer Institute. Foreign grant applications will also be reviewed by the National Cancer Advisory Board.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the NCI. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Ms. Diane Bronzert or Dr. Roy Wu
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Direct inquiries regarding fiscal matters to:

Ms. Eileen Natoli
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 56
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended, Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

RICHARD W MURRY

* 340:89
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

Vol. 23, No. 12
March 25, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

FINAL FINDINGS OF SCIENTIFIC MISCONDUCT

NIH GUIDE, Volume 23, Number 12, March 25, 1994

P.T.

Public Health Service

Notice is hereby given that on February 25, 1994 a Research Integrity Adjudications Panel of the Departmental Appeals Board issued a ruling upholding scientific misconduct findings of the Office of Research Integrity (ORI) in the following case:

John C. Hiserodt, M.D., Ph.D., University of Pittsburgh. An inquiry conducted by the university and an investigation conducted by the Office of Research Integrity found that Dr. Hiserodt deliberately and knowingly falsified four figures and one table in two research grant applications submitted to the National Institutes of Health, and deliberately and knowingly fabricated a laboratory notebook to cover-up the falsifications in the grant applications. In reporting research results on antigen recognition by natural killer cells, Dr. Hiserodt falsely reported that a purportedly unique protein had a molecular weight of 48 kilodaltons by altering photographs of autoradiograms, falsely reported that this protein had been found in human cells, falsely reported the results of a gene sequence in response to questions raised by NIH grant reviewers about his experimental findings, and fabricated a laboratory notebook to cover-up the falsified research when questions about it were raised by investigating officials.

Dr. Hiserodt has been debarred from receiving Federal grant or contract funds for a period of five years beginning March 9, 1994. In addition, any institution receiving PHS research support involving Dr. Hiserodt must monitor the accuracy of his research for an additional two-year period following the five-year debarment (for a total period of seven years) beginning March 9, 1999. He has also been prohibited from serving on PHS Advisory Committees or review groups for seven years beginning February 25, 1994. Dr. Hiserodt is also required to request correction of the article "The Expression and Functional Involvement of Laminin-like Molecules in Non-MHC Restricted Cytotoxicity by Human Leu-19+/CD3-Natural Killer Lymphocytes," Journal of Immunology, Vol. 141, 3318-23, 1988, to indicate that Figure 2 in the article may not be relied upon.

INQUIRIES

The Office of Research Integrity will continue to publish findings of scientific misconduct as further cases are closed. For further information, contact:

Director
Division of Research Investigations
Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, MD 20852
Telephone: (301) 443-5330

VOLUNTARY PROVISION OF INFORMATION ON BIOMARKERS AND INTERMEDIATE ENDPOINTS IN PREVENTION TRIALS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

P.T.

National Cancer Institute

The National Cancer Institute (NCI) announces the establishment of a biomarker registry comprised of information that may be useful to investigators when biomarkers are being considered as intermediate endpoints or as outcome measures in prevention trials. In an effort to collect information on biomarkers, the NCI seeks cooperation from the extramural scientific community on a voluntary basis. Information may be submitted by anyone currently engaged in biomarker research.

The following characteristics of biomarkers are of interest:

1. **Biological Characteristics:** The description should include, but is not limited to, the spontaneous biological rate of progression and/or regression, site-specificity, histology, chromosomal aberrations, epigenetic changes, mutations, histologic correlation, and the phase, i.e., whether the marker in question occurs at an early, intermediate, or late stage of the carcinogenesis process.
2. **Outcome Association:** Provide information on population, subjects, sites, intermediate endpoints, and the rate of regression of intermediate endpoints in a given time frame in response to the intervention (e.g., 50 percent regression in two months). In the case of chemoprevention trials, also provide the name of the chemopreventive agent, dose (including toxicity data), preclinical efficacy, preclinical safety, clinical safety, and the clinical efficacy, if known.
3. **Epidemiological Characteristics:** Provide information on (1) types of marker: (a) biomarkers of susceptibility, (b) biomarkers of exposure, (c) biomarkers of biological effects, (d) biomarkers of disease cancer; (2) source of variability: sampling variability, inter- and intra-individual variability, inter- and intra-observational variability, and time-dependent variability; (3) study design: case-control, prospective cohort, or randomized trial. Provide the material for the choice of the endpoint and sample size in your study.

INQUIRIES

For further information, contact

Barnett S. Kramer or Sudhir Srivastava
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 305
Bethesda, MD 20892
Telephone: (301) 496-8544
FAX: (301) 496-8667

NATIONAL HUMAN SUBJECT PROTECTIONS WORKSHOP

NIH GUIDE, Volume 23, Number 12, March 25, 1994

P.T.

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

DATES: April 27-28, 1994

LOCATION

Magovern Conference Center, Allegheny General Hospital, Pittsburgh, PA

SPONSORS

Allegheny-Singer Research Institute, Pittsburgh, PA
Delaware State College, Dover, DE

REGISTRATION

Ms. Kathleen Hrdlicka
Continuing Medical Education
Allegheny General Hospital
320 E. North Avenue
Pittsburgh, PA 15212
Telephone: (412) 359-4952

TITLE: Contemporary Issues in Human Subject Protection

DESCRIPTION: The protection of human subjects is the fundamental responsibility of institutional review boards. Today there are many challenges facing IRBs and research investigators in accomplishing this objective. This Workshop will focus on current legal, ethical, and media issues related to human subjects participating in research. Emphasis will be directed at risk assessment (including mechanisms to minimize risk), research fundamentals, regulatory updates, and a special session will address the impact of the media on biomedical research. The format for the Workshop will include large and small group didactic presentations and panel discussions providing a forum for audience participation.

DATES: July 11, 12, 13, 1994

LOCATION

Mall of American Grand Hotel, Bloomington, MN

SPONSORS

University of Minnesota of Minneapolis, Minneapolis, MN
American Indian Health Care Association, St. Paul, MN
Indian Health Service, Albuquerque, NM

CONTACT

Office of Continuing Medical Education
University of Minnesota
Radisson Hotel Metrodome, Suite 107
615 Washington Avenue, SE
Minneapolis, MN 55414
Telephone: (612) 626-7600 or (800) 776-8636

TITLE: Contemporary Issues on Existing and New Research Guidelines on Women and Minority Groups: Special Emphasis on American Indians

DESCRIPTION: The Conference will examine existing NIH research guidelines, and discuss contemporary issues in the research environment. There will be IRB training; conference participants will be in small mock IRBs to review three protocols, with facilitation by experienced IRB staff. The Conference will examine how protecting American Indian individuals and communities by IRBs and community participation: (1) increases research benefit, (2) decreases research risk, and (3) improves quality of the research. Because Native (American Indian and Canadian First Nation) people are

covered by the new NIH guidelines about inclusion of women and minorities in research, the Conference will also examine that policy in depth. The focus on Native communities and volunteers will illuminate how the new Guidelines, current IRB regulations, and community involvement fit together in practice.

INQUIRIES

For further information regarding these workshops or future NIH/FDA National Human Subject Protections Workshops, contact:

Ms. Darlene M. Ross
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

EXPIRED BREATH ANALYSIS IN CHEMICAL TOXICITY ASSESSMENT

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFP AVAILABLE: NIH-ES-94-27

P.T.

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting proposals from offerors that have the capabilities and facilities for the following: Phase 1 -- Using the methodology developed under the contract N01-ES-05290 "Expired Breath Analysis in Chemical Toxicity Assessment," the contractor design of a series of experiments to determine changes in the relative production rate (normalized to CO2 production) of the various breath components in male or female F344 rats exposed to various chemical treatments. These treatments will include specific inhibitors or inducers of as many cytochrome P450 isoforms as can be evaluated in the rat, including forms of the enzymes involved in steroid metabolism. The contractor will propose experiments to study the effect of modulation of tissue glutathione levels in relation to changes in expired breath components; Phase 2 will consist of one of two selected tasks.

The Government estimates that the project will require approximately 1.5 professional person-years per contract year. The estimated period of performance is three years.

INQUIRIES

Release of the RFP is anticipated on or about March 21, 1994 with proposals due May 2, 1994. All responsible sources may submit a proposal that will be considered by the Agency. Requests must reference RFP No. NIH-ES-94-27 and must be directed to:

Howard Hill
Contracts and Procurement Management Branch
National Institute of Environmental Health Sciences
79 T.W. Alexander Drive, Building 4401 Research Commons
P.O. Box 12874
Research Triangle Park, NC 27709
Telephone: (919) 541-4971
FAX: (919) 541-2712

DETAILED DRUG EVALUATION OF TREATMENT STRATEGIES FOR CHEMOTHERAPEUTIC AGENTS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFP AVAILABLE: NCI-CM-57207-30

P.T.

National Cancer Institute

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) is seeking a contractor to evaluate compounds for anticancer activity in experimental in vivo tumor models. Studies will focus on agents identified by the Program's disease-oriented in vitro drug screen and will employ human tumors growing in immune-deficient (e.g., athymic, SCID) mice. Experiments will be designed and conducted to optimize drug activity and evaluate the drug's therapeutic potential. Some in vivo studies may involve murine tumors growing in pathogen-free immune-competent rodents, and some cell culture support will be required for propagation of selected human tumors. Results from the project will be interrelated with pharmacokinetic, toxicologic, biochemical and immunologic information to devise and recommend treatment strategies for clinical trials and will be included in investigational New Drug Applications.

Compounds to be studied will be selected and assigned by the Government. As compounds of a commercially confidential nature may be evaluated, pharmaceutical and chemical companies will be excluded from the competition. Also, since structural formulae of confidential materials may be provided by the Government on occasion, the organization must be willing to sign a confidentiality of information statement.

The organization will provide facilities for handling pathogen-free immune-competent and immune-deficient rodents and utilize methods to protect the facilities from pathogenic organisms. The contract also shall provide facilities/equipment for frozen storage of tumors, tumor transplantation, drug preparation, and treatment, facilities/equipment for the handling of potentially carcinogenic or hazardous materials; facilities/equipment for propagation and testing human and murine tumor lines in vitro. The Principal Investigator should have an M.D.; D.V.M.; or Ph.D. in one of the relevant biological sciences (or equivalent experience), managerial experience, and experience in either managing an in vivo screening program utilizing small animals or evaluating the efficacy or toxicity of antitumor agents, should understand the principles of cancer chemotherapy, and devote approximately 25 percent of his/her time to the project.

It is anticipated that one incrementally funded contract will be awarded for a base period of three years, with two one year options. The contract will be written on a level-of-effort basis, specifying that the contractor is to furnish 64,000 labor hours over five years. RFP No. NCI-CM-57207-30 will be available on or about March 31, 1994. Responses will be due May 20, 1994.

INQUIRIES

Copies of the RFP may be obtained by sending a written request to:

Ms. Elsa B. Carlton
Research Contracts Branch
National Cancer Institute
Executive Plaza South, Room 603
Bethesda, MD 20892
Telephone: (301) 496-8620

No collect calls will be accepted.

MENTAL RETARDATION RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: HD-94-020

P.T.

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: May 15, 1994

Application Receipt Date: July 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD), through the Mental Retardation and Developmental Disabilities (MRDD) Branch, Center for Research for Mothers and Children (CRMC), invites research center core grant applications to develop new knowledge in the field of prevention, treatment, and amelioration of mental retardation and developmental disabilities. Four centers may be supported in response to this RFA.

The primary objective of the NICHD Mental Retardation Research Centers (MRRCs) is to provide support and facilities for a cohesive, interdisciplinary program of research and research training in mental retardation and related aspects of human development. The NICHD has supported MRRCs through the provision of core grants, which facilitate program coordination and support central research core facilities. Funds for the research projects using these core units come from independent sources including Federal, State, and private organizations. This RFA seeks applications from existing MRRCs and from other institutions that have a comparable concentration of research in mental retardation.

A major goal of the MRDD Branch's research program is to prevent and/or ameliorate mental retardation. In general, the degree of impairment associated with mental retardation varies in relation to the cause. Moderate and more severe mental retardation often results from problems that produce profound alterations in brain development and/or function. Diminished intellectual and adaptive capacity can often be traced to defective genes, teratogenic agents, infections, nutritional deficits, accidents, diseases and other disorders causing brain damage. A larger proportion of cases of mental retardation is related to environmental conditions and disorders of unknown etiology. These complex problems require integrated multidisciplinary approaches involving biomedical and behavioral sciences in a variety of settings.

The purpose of a Mental Retardation Research Center is to provide a research environment that facilitates interdisciplinary collaboration among investigators who are working in areas of relevance to the prevention and amelioration of mental retardation. Such research will cover a broad spectrum of scientific approaches ranging from laboratory research on fundamental processes of abnormal development to clinical and educational research in which persons with mental retardation are studied.

It is thought that major solutions to the problems of mental retardation may be found as a result of multidisciplinary collaboration involving a variety of approaches in the MRRCs. As a result of the administrative and scientific organization within an MRRC and across the network of MRRCs, opportunities for breakthroughs will be enhanced.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Mental Retardation Research Centers, is related to several priority areas including nutrition, alcohol and other drugs, mental health and mental disorders, environmental health, maternal and fetal health, HIV infection, and immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-011-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, and units of State or local governments. As stated in the NICHD Center Guidelines, the NICHD will not support more than one center grant in a given department or specialty unit.

MECHANISM OF SUPPORT

Mental Retardation Research Center grants will be supported through the center core grant (P30) mechanism. The application should be prepared in a manner consistent with the general guidelines presented in the publication, P30 CENTER CORE GRANT GUIDELINES, which are available from the NICHD office listed under INQUIRIES.

Awards will be made for a period of five years. To be eligible for award as an MRRC, the Center must provide core support for a minimum of 10 projects funded from non-university sources.

The total direct costs requested for the first year of a new Center Core Grant (P30) should not exceed \$500,000. Renewal applications from existing P30 Centers may request initial year direct costs up to, but not exceeding, 120 percent of the Notice of Grant Award level of direct costs for the final year of the preceding project period, or \$500,000 direct cost, whichever is greater. Budgets of applications for new and renewal support will be stringently reviewed within these guidelines. Applications with budget requests exceeding these guidelines will be returned to the applicant without review.

FUNDS AVAILABLE

This is the seventh in a series of annual announcements. Plans are to make four awards in fiscal year 1995. The estimated funds available for the first year of support for the entire program is \$3.3 million total costs. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

MRRC Core Grants are intended to bring together in a center a variety of disciplines to work on the common problems of mental retardation. Consequently, applications for Mental Retardation Center Core Grants (P30) should include investigators studying a range of topics in basic and clinical or applied research. Applicants are encouraged, but are not required, to include both biomedical and behavioral components from among, but not limited to, the following topics:

1. Developmental neurobiological studies relevant to MRDD.
2. Inborn errors of metabolism relevant to MRDD.
3. Genetic/cytogenetic disorders associated with MRDD.
4. Molecular biology; development of animal models.
5. Toxicology and physical environmental factors in the etiology, treatment and prevention of MRDD.
6. Intellectual, behavioral, physical and the intergenerational effects of malnutrition.
7. Developmental pharmacology and psychopharmacology.
8. Infectious diseases in the etiology, prevention and treatment of MRDD.
9. Diagnosis: identification of, and early intervention for, infants and children at risk to develop MRDD.
10. Perinatal problems associated with MRDD.
11. Psychobiological processes in MRDD.
12. Psychological processes in MRDD.
13. Behavioral analysis of individuals with MRDD.
14. Family and community studies.
15. Language and communication studies.
16. Learning disabilities, dyslexia, and attention deficit disorder.
17. Behavior in residential, educational, and occupational settings.
18. Socioeconomic status, ethnicity, and ecological processes.
19. Epidemiology of MRDD.
20. Behavior and life-styles that could affect mortality and morbidity.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 15, 1994, a letter of intent that includes a descriptive title, the name, address, and telephone number of the principal investigator, the names of other key personnel and participating institutions, the core unit directors and principal investigators of the research projects that would use the core units, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in evaluating relevance to MRDD and in planning for the review of applications.

The letter of intent is to be sent to Dr. Felix F. de la Cruz at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted using PHS 398 (rev. 9/91). Application kits containing this form and the necessary instructions are available in most institutional offices of sponsored research and may be obtained from the Office of Grant Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The NICHD recommends that the application be developed in consultation with the MRDD Program staff, CRMC, who will provide whatever guidance is possible and appropriate in relation to both scientific and administrative issues. The completed application must be submitted to the Division of Research Grants by July 15, 1994.

REVIEW CONSIDERATIONS

Applications received in response to this RFA will be reviewed with each other on a nationwide competitive basis. The initial review for scientific merit will be carried out by the NICHD Mental Retardation Research Committee (MRRC) at its March 1995 meeting. Because a site visit is not a prerequisite for MRRC consideration, each application should be thorough and complete enough to stand on its own. The second-level review will be made by the National Advisory Child Health and Human Development Council at its June 1995 meeting. The earliest possible funding will be August 1995.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Felix F. de la Cruz, M.D., M.P.H.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 48-09
Bethesda, MD 20892
Telephone: (301) 496-1383

Direct inquiries regarding fiscal matters to:

Mr. Edgar D. Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A-17
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 13.865 Research for Mothers and Children. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

COOPERATIVE MULTICENTER REPRODUCTIVE MEDICINE NETWORK

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: HD-94-016

P.T.

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: May 1, 1994

Application Receipt Date: July 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate, with the assistance of NICHD under cooperative agreements, in an ongoing multicenter cooperative program designed to conduct clinical studies investigating problems in adult reproductive medicine.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cooperative Multicenter Reproductive Medicine Network, is related to the priority area of family planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private. Minority individuals, persons with disabilities, and women are encouraged to apply. The need for continuous and active communication among sites dictates that only institutions in the United States will be eligible for participation.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U10), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Details of the responsibilities, relationships and governance of the study to be funded under cooperative agreements are discussed in the RFA under "Terms and Conditions."

Cooperative agreements are assistance mechanisms and are subject to the same administrative requirements as grants. The special Terms of Award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS, PHS, and NIH grant regulations, policies and procedures at 45 CFR Part 74 and 92, and other HHS, PHS, and NIH grant administration policies.

The total project period for applications submitted in response to the present RFA may not exceed five years. The anticipated award date is April 1, 1995. At this time, the NICHD has not determined whether this solicitation will be continued beyond the present RFA.

FUNDS AVAILABLE

It is anticipated that one award for the Data Coordinating Center and eight awards for Clinical Sites will be made, with an estimated total of \$1,800,000 (including direct and indirect costs) for the entire program in the first year. Up to five competing continuation awards and at least four new awards are expected. Although this program is provided for in the financial plan of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

There are a number of unresolved questions in reproductive medicine that would lend themselves to cooperative study. The following should by no means be viewed as exclusive, and are intended only as examples:

- o In vitro fertilization: Patient selection, comparison of treatment protocols to optimize live birth rates.
- o Endometriosis: Controlled trials of diagnostic methods and treatments.
- o Polycystic ovarian syndrome: Definition, subgroups, response to therapies.
- o Leiomyomata: Controlled trials of diagnostic methods and treatments.
- o Varicocele: Effect on fertility, benefits of surgery.
- o Male infertility: Diagnosis and treatment directed at the male.

The Network will include approximately eight clinical sites or "Reproductive Medicine Units" (RMUs) and a Data Coordinating Center (DCC). There will be two domains within the Network: Infertility/Andrology, and Gynecology. "Infertility" is intended to encompass male factor, female factor, and unknown cause. It is anticipated that initial Network activity would encompass one protocol from each domain, with one RMU acting as lead unit for each protocol. The RMUs will recruit, evaluate and treat the participants in either or both of the clinical studies. The Data Coordinating Center will have primary responsibility for data collection and management for each trial.

A Steering Committee will consist of the principal investigators, the NICHD Research Coordinator, and a chairperson designated by the Steering Committee. The Steering Committee will develop by consensus the protocols to be carried out under these cooperative agreements, and supervise the conduct of the studies.

A Data Safety and Monitoring Committee convened by the NICHD will have responsibility for reviewing proposed clinical protocols, and for making a recommendation to the NICHD whether to accept, modify, or decline such proposed studies.

SPECIAL REQUIREMENTS

The NICHD invites applications both from current members of the Network (competing renewal applications) and from prospective members (new applications). Minimum requirements for applicants are described in detail in the RFA (see INQUIRIES). Before requesting the RFA, potential RMU applicants should note that they must have a history of previous successful clinical research and expertise in research design, biostatistics, and the use of clinical protocols. They must also be able to demonstrate ability to enroll sufficient numbers of patients for meaningful studies and excellence in collecting and maintaining clinical data. Potential DCC applicants must have demonstrated prior experience as a Coordinating Center in multicenter studies.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Donna L. Vogel at the address listed under INQUIRIES.

APPLICATION PROCEDURES

All applicants must document their ability to meet or exceed the minimum requirements as set out in the SPECIAL REQUIREMENTS section for RMU or DCC applications in the RFA.

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these awards. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applications must be received by July 19, 1994. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness and responsiveness by NIH staff. Incomplete applications will be returned to the applicant without further consideration. Any application that does not meet the minimum requirements of this RFA will be considered unresponsive to the RFA and returned to the applicant.

Applications may receive a preliminary scientific peer review (triage) by an NICHD peer review group to determine their relative competitiveness. The NIH will withdraw from further competition those applications judged to be noncompetitive for award and notify the applicant Principal Investigator and institutional official.

Those applications judged to be competitive will undergo further evaluation for scientific merit by an appropriate peer review group convened by the NICHD, according to the criteria listed in the RFA, including: qualifications, experience, and commitment of Key Personnel; protocols and procedures; and facilities and management. The second level of review will be provided by the National Advisory Child Health and Human Development (NACHHD) Council.

AWARD CRITERIA

The anticipated date of award is April 1, 1995. Applications recommended by the NACHHD Council will be considered for award based on scientific and technical merit, program balance, and availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Donna L. Vogel, M.D., Ph.D.
Reproductive Sciences Branch
National Institute of Child Health and Human Development
Building 61E, Room 8801
Bethesda, MD 20892
Telephone: (301) 496-6515
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 61E, Room 8817
Bethesda, MD 20892
Telephone: (301) 496-5481
FAX: (301) 402-0915

AUTHORITY AND REGULATIONS

This Program is described in the Catalog of Federal Domestic Assistance number 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title X, Section 1004 (Public Law 92-572, as amended; 42 USC 241) and Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241). These special Terms of Award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Part 74, and other HHS, PHS, and NIH grant administration policies. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

TROPICAL DISEASE RESEARCH UNITS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: AI-94-019

P.T.

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: May 23, 1994

Application Receipt Date: July 21, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Parasitology and Tropical Diseases Branch, Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID) invites applications for program project grants to conduct multidisciplinary research leading to the development and evaluation of new strategies to prevent and control diseases caused by protozoan and helminth parasites. Programs will focus on one of the following areas: (1) development of vaccines for infection and disease; (2) discovery of drug targets and development of new chemotherapeutic agents for treating and preventing parasitic infections; or (3) development of new approaches for interruption of the parasite life cycle at the level of the invertebrate (vector) host.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Tropical Disease Research Units, is related to the priority areas of immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Only domestic organizations are eligible to apply for program project (P01) grants. Applications may be submitted by domestic for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanism of support will be the program project (P01) grant. This is a mechanism for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. An important feature of the program project is that the interrelationships of the individual scientifically meritorious projects will result in a greater contribution to the overall program goals than if each project were pursued individually. The program project grant consists of a minimum of three interrelated individual research projects that contribute to the program objective. The program project grant also can provide support for certain common resources termed cores. Such resources should be utilized by two or more projects within the program project.

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period may not exceed five years. These P01 applications may not request budgets in excess of \$500,000 direct costs in the first year and may not request more than four percent annual inflationary increases for future years.

FUNDS AVAILABLE

The estimated minimum total funds (direct and indirect costs) available for the first year of this program will be \$2.4 million. In fiscal year 1995, the NIAID plans to fund at approximately three to four program projects related to this award.

RESEARCH OBJECTIVES

Background

Parasitic diseases continue to represent tremendous public health problems, especially for people living in the tropics where parasites are responsible for deaths and impaired growth and development of children and debilitating, chronic diseases among adults. Additionally, parasitic infections have been increasingly recognized as responsible for diseases in the United States and other industrialized countries. Of special interest is the occurrence of severe disease in individuals who acquired an infection congenitally or as a result of immunosuppression.

This RFA represents a continuation of the Tropical Disease Research Units (TDRU) program, which was designed to stimulate advanced biomedical research on five parasitic diseases (filariasis, leishmaniasis, malaria, schistosomiasis, and trypanosomiasis). Recent advances in our understanding of the basic biology of these parasites and of host-parasite interactions have created unique opportunities for discovering and evaluating new means of controlling the mortality and morbidity associated with parasitic infections. The NIAID recognizes that substantial advances have been made in the understanding of other parasitic diseases that also represent significant global public health concerns. Thus, for

the purposes of this recompetition, the NIAID will expand the scope of the TDRU program to encompass all medically important human parasitic diseases. TDRUs will provide a resource for concerted efforts for the development and preclinical testing of new intervention strategies for parasitic diseases.

Scope of Research

The NIAID wishes to support multidisciplinary, state-of-the-art biomedical research units to serve as foci for innovative research on medically important parasites or their vectors, leading to new intervention strategies to control the public health impact of diseases caused by protozoa and helminths. For the purpose of this RFA, intervention strategies to be considered are: (1) vaccines to prevent infection and/or disease; (2) chemotherapeutic agents to prevent and/or treat infection; and (3) methods to control invertebrate vectors or interrupt the parasite's life cycle in the vector.

The entire program project grant, consisting of three or more projects as well as cores, must address the development of one of these intervention strategies. While limited to a single intervention strategy, the program project may focus, however, on one or more parasitic infections. Each application must provide an experimental plan which details the methods that will be used to validate the utility of the chosen approach. Programs may involve collaboration among investigators at several institutions. Consortium arrangements should follow the NIH Guide outline in "Guidelines for Establishing and Operating Consortium Grants, January 1989." These are available from the individuals listed under INQUIRIES.

SPECIAL REQUIREMENTS

Institutions receiving TDRU awards are considered as Centers in the NIAID International Centers for Tropical Disease Research network and TDRU program directors are designated as Center Directors in this network. The application should budget appropriate funds to allow the TDRU program director to attend the annual meeting of the network, which is generally held in Bethesda in the Spring.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 23, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. The letter of intent is not required. It allows NIAID staff to estimate the potential review workload and avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892. Applicants for Program Project Grants should read the information brochure "NIAID Program Project and Multiproject Cooperative Agreements" available from Michael Gottlieb at address listed under INQUIRIES.

REVIEW CONSIDERATIONS

Applications will be reviewed by Division of Research Grants (DRG) staff for completeness and by NIAID staff to determine administrative and programmatic responsiveness to this RFA. Those judged to be incomplete or nonresponsive will be returned to the applicant without review. Those considered complete and responsive may be subjected to a triage review by an NIAID peer review group to determine their scientific merit relative to the other applications. The NIAID will withdraw from competition those applications judged by the triage peer review group to be noncompetitive for award and will so notify the applicant investigator and the institutional business official. Those applications judged to be competitive for award will be reviewed for scientific and technical merit by a Review Committee convened by the Division of Extramural Activities, NIAID. The second level of review will be provided by the NIAID Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify issues or questions from potential applicants is welcome. Requests for the RFA and the brochure entitled "NIAID Program Project and Multiproject Cooperative Agreements" as well as inquiries regarding programmatic issues may be directed to:

Dr. Michael Gottlieb
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A03
Bethesda, MD 20892
Telephone: (301) 496-7115
FAX: (301) 402-0804
E-Mail: mg35s@nih.gov

Direct inquiries regarding the review of applications and address the letter of intent to:

Dr. Olivia Preble
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C19
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Leslie Marsden
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B29
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

Letter of Intent Receipt Date: May 23, 1994
Application Receipt Date: July 21, 1994
Scientific Review Date: November 1994
Advisory Council Date: February 1995
Earliest Date of Award: May 1995

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Sec. 301 (c), Public Law 78-410, as amended. The Catalogue of Federal Domestic Assistance Citation is Sec. 93.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.

VAGINAL IMMUNOLOGY: INTERACTION WITH INTRAVAGINAL PRODUCTS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: HD-94-017

P.T.

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: May 31, 1994
Application Receipt Date: July 27, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites research grant applications for the support of basic and applied research to evaluate the affect of intravaginal products, treatments and spermicides on vaginal immunology. An important part of the mission of the NICHD is to gain new knowledge about human reproduction, especially those that may lead to new approaches to contraception. This RFA is intended to address that charge.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Vaginal Immunology: Interaction with Intravaginal Products, is related to the priority area of primary prevention of sexual spread of HIV infection with the use of topical microbicides and contraceptives. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9352 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Minority individuals, persons with disabilities, and women are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01) and FIRST (R29) award as the support mechanisms. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The

earliest expected award date is March 1, 1995.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will also vary.

FUNDS AVAILABLE

It is expected that up to five new applications will be funded, within the total cost limit of \$1,000,000 available for the first year. This level of support is dependent on the receipt of sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

For the purpose of this RFA, research subject areas would include, but not be limited to, the following:

- o Delineate how endocrinologic and biological factors such as exogenous hormones (oral contraceptives, time of the menstrual cycle, pregnancy, and menopause affect the mucosal immune response in the reproductive tract and alter an HIV-negative woman's susceptibility to HIV infection or an HIV-positive woman's infectiousness.

- o Delineate characteristics influencing the concentration and activation of lymphoid cells in the vagina when exposed to semen.

lactobacilli on the local immune responses as a mechanism to resist disease.

- o Determine how and whether spermicides, douches, and topical agents (antibiotics, antifungals etc) affect the vaginal/cervical secretory or cell-mediated immune responses.

- o Determine what characteristics are desirable in a formulation of a topical drug to maintain or enhance mucosal cell-mediated or secretory immune responses.

NOTE: The use of STDs as a model to understand vaginal immunology is outside the scope of this RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are strongly encouraged, but not required, to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid conflict of interest circumstances in the review process.

The letter of intent is to be sent to Dr. Pamela Stratton at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must be received by July 27, 1994. If an application is received after that date, it will be returned to the applicant.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, it will be returned to the applicant, who may then submit it to DRG for review in competition with unsolicited applications at the next available review cycle.

Responsive applications may be triaged by a peer review group to determine their relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further evaluation for scientific merit in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the National Advisory Child Health and Human Development (NACHHD) Council.

Review criteria for RFAs are generally the same as those for unsolicited research grant applications. For studies in HIV-infected women, documented collaboration with ongoing epidemiologic studies of HIV-infected women, including but not limited to the Women and Infants Transmission Study (WITS), the Women's Interagency HIV Study, and the HIV Epidemiologic Research Study (HERS). For studies of any other cohort of women, documented collaboration with gynecologists or other clinicians who have access to the number and type of women who are proposed to be studied.

AWARD CRITERIA

The anticipated date of earliest award is February 1, 1995. Funding decisions will be based on peer review and NACHHD Council recommendation, program relevance, and availability of funds. In some cases, if the proposed research has relevance to other Institutes of the National Institutes of Health, the application may be dually assigned to, and considered for funding by, the NIAID. Any such assignment will be made independently of peer review procedures.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are encouraged.

Direct requests for the RFA, inquiries regarding scientific issues, and address the letter of intent to:

Pamela Stratton, M.D.
Contraceptive Development Branch
National Institute of Child Health and Human Development
Building 6100, Room 8B13
Bethesda, MD 20892
Telephone: (301) 496-1661
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12374 or health Systems Agency review.

VAGINAL PHYSIOLOGY: INTERACTION WITH INTRAVAGINAL PRODUCTS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: HD-94-018

P.T.

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: May 31, 1994
Application Receipt Date: July 27, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites research grant applications for the support of basic and applied research to evaluate the affect of intravaginal products, treatments and spermicides on vaginal physiology. An important part of the mission of the NICHD is to gain new knowledge about human reproduction, especially those that may lead to new approaches to contraception. This RFA is intended to address that charge.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Vaginal Physiology: Interaction with Intravaginal Products, is related to the priority area of primary prevention of sexual spread of HIV infection with the use of topical microbicides and contraceptives. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9352 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Minority individuals, persons with disabilities, and women are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01) and FIRST (R29) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest expected award date is March 1, 1995.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will also vary.

FUNDS AVAILABLE

It is expected that up to five new applications will be funded, within the total cost limit of \$1,000,000 available for the first year. This level of support is dependent on the receipt of sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

For the purpose of this RFA, research subject areas would include, but not be limited to, the following:

- o Identify the physical and chemical interactions throughout the menstrual cycle that occur between vaginal bacteria and the underlying epithelium. One approach is to consider the nutrients microorganisms need and to evaluate how the vaginal microenvironment supplies these requirements. These include nutritional substrates, need for appropriate physical environment (temperature, pH, hydration and oxygen tension) and the ability to survive in the presence of antibacterial factors produced by the host or other microbial species.
- o Delineate characteristics of normal vaginal physiology such as the amount of vaginal fluid released in the vagina during sexual excitement or how fast the vaginal epithelium is exfoliated and replaced.
- o Assess the value of artificial colonization with bacteria such as lactobacilli as a mechanism to resist disease.
- o Delineate endocrinologic or biological factors that may affect host susceptibility or infectiousness to HIV in vaginal and cervical mucosal tissues: e.g., time of the menstrual cycle, pregnancy, menopause, or exogenous hormones. Define the role of antiviral defense mechanisms in HIV transmission, e.g., low pH, lysozyme, hydrogen peroxide, and lactoferrin in vaginal fluids.
- o Determine how spermicides, douches, and topical or systemic agents (antibiotics, antifungals, etc.) affect the vaginal environment. Does use of any topical spermicides or microbicides reduce the infectiousness of seropositive women?
- o Determine how different formulations affect a product's activity in the vagina in terms of time required for activation, effect of pH on activity, or interaction with cervical mucus.
- o Determine what characteristics are desirable in a formulation of a topical drug including interaction with the vaginal environment, time to onset of activity, and limits on frequency of application.

Note: The use of sexually transmitted diseases or human immunodeficiency virus infection as a model is not within the scope of this RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are strongly encouraged, but not required, to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid conflict of interest circumstances in the review process.

The letter of intent is to be sent to Dr. Pamela Stratton at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must be received by July 27, 1994. If an application is received after that date, it will be returned to the applicant.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, it will be returned to the applicant, who may then submit it to DRG for review in competition with unsolicited applications at the next available review cycle.

Responsive applications may be triaged by a peer review group to determine their relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applicant judged to be competitive will undergo further evaluation for scientific merit in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the National Advisory Child Health and Human Development (NACHHD) Council.

Review criteria for RFAs are generally the same as those for unsolicited research grant applications. For studies in HIV-infected women, documented collaboration with ongoing epidemiologic studies of HIV-infected women, including but not limited to the Women and Infants Transmission Study (WITS), the Women's Interagency HIV Study, and the HIV Epidemiologic Research Study (HERS). For studies of any other cohort of women, documented collaboration with gynecologists or other clinicians who have access to the number and type of women who are proposed to be studied.

AWARD CRITERIA

The earliest anticipated date of award is March 1, 1995. Funding decisions will be based on peer review and NACHHD Council recommendation, program relevance, and availability of funds. In some cases, if the proposed research has relevance to any other Institute of the National Institutes of Health such as the National Institute of Allergy and Infectious Diseases, the application may be dually assigned to, and considered for funding by, the other institute. Any such assignment will be made independently of peer review procedures.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are encouraged.

Direct requests for the RFA, inquiries regarding scientific issues, and address the letter of intent to:

Pamela Stratton, M.D.
Contraceptive Development Branch
National Institute of Child Health and Human Development
Building 6100, Room 8813
Bethesda, MD 20892
Telephone: (301) 496-1661
FAX: (301) 496-0962

Direct inquires regarding fiscal matters to:

Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12374 or health Systems Agency review.

NIH GUIDE, Volume 23, Number 12, March 25, 1994

RFA AVAILABLE: AI-94-014

P.T.

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: July 15, 1994

Application Receipt Date: August 11, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Developmental Therapeutics Branch (DTB) of the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), invites applications from a combination of academic, non-profit research, and commercial organizations focused on the discovery and rational design of new therapies with potential to treat and/or prevent specific opportunistic infections (OIs) in individuals infected with HIV. Opportunistic pathogens targeted in this RFA are human cytomegalovirus (HCMV), *Mycobacterium tuberculosis*, *Mycobacterium avium*, *Pneumocystis carinii*, *Cryptosporidium parvum*, *Toxoplasma gondii*, the microsporidia (e.g., *Enterocytozoon bienersi*, *Septata intestinalis*), and *Cryptococcus neoformans*. Research activities should be directed toward discovery of selective drugs or molecular strategies that are lethal to the pathogen with minimal toxicity for the host. Applications that include research projects or core components from the private sector are encouraged. No clinical trials will be supported under this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections Associated with AIDS (NCDDG-OI) including Tuberculosis, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private organizations such as universities, colleges, hospitals, laboratories, units of State or local government, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to undertake this program will be the cooperative agreement (U19), an "assistance" mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated. Essential elements of the U19 mechanism include: (1) a minimum of three inter-related research projects organized around a central theme; (2) collaborative efforts and interaction among independent projects and their investigators to achieve a common goal; and (3) "Core" resources or facilities, each of which is expected to be utilized by at least two research projects. Details of the responsibilities, relationships, and governance of a study funded under cooperative agreement(s) are discussed in the RFA under the section Terms and Conditions of Award. The total project period for applications may not exceed four years. The anticipated award date is April/May 1995.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards under this RFA reissuance will be \$5.6 million. Applications received with budgets in excess of \$700,000 first-year total costs will be returned without review. In Fiscal Year 1995, the NIAID plans to fund at least one group each for drug discovery against these high priority OIs: HCMV, *Mycobacterium tuberculosis*, *Mycobacterium avium*, *Pneumocystis carinii*, *Cryptosporidium parvum*, *Toxoplasma gondii*, the microsporidia (e.g., *Enterocytozoon bienersi*, *Septata intestinalis*), and *Cryptococcus neoformans*.

RESEARCH OBJECTIVES

The purpose of this RFA is to foster multi-disciplinary research projects aimed at the discovery and rational design of new therapies against the OIs associated with AIDS. The objective of this RFA is to stimulate drug discovery through original and innovative research focused on the microbiology, molecular biology, chemistry, computer-assisted drug design, drug delivery vehicles, and animal models that will lead to the identification of new drug targets. Research objectives in this RFA reissuance include, but are not necessarily limited to:

- o the discovery and development of effective therapies to treat high priority opportunistic infections associated with AIDS;
- o identification and characterization of new molecular targets for exploitation toward selective virucidal, mycobactericidal, parasiticidal, and fungicidal therapeutic agents;
- o establishment and utilization of in vitro assays for selected molecular targets to identify compounds and biologicals;

- o refinement of novel and innovative animal models to evaluate the therapeutic potential of new compounds and to compare efficacy in normal and immunocompromised models;
- o development of improved methodologies or surrogate markers for assessing therapeutic efficacy in animal models;
- o elucidation of mechanisms of drug resistance and study of strategies to overcome such resistance.

SPECIAL REQUIREMENTS

All applications must consist of at least three interrelated projects conducted by at least three independent laboratories focusing on a unifying central theme. For the purpose of encouraging new collaborations under this RFA, two (or more) projects within a single company will not be considered independent. Similarly, two (or more) projects within the same academic department will not be considered independent. Random or large scale screening as well as clinical trials will not be supported under this RFA. A minimum 10 percent (time) effort by the Principal Investigator and each Project Leader should be devoted to the study, unless there are compelling arguments to the contrary.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 15, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, the number and title of this RFA, and a list of the key investigators and their institution(s) and projects. The letter of intent is to be sent to Dr. Dianne Tingley at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the research grant application form PHS 398 (rev. 9/91). For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "NATIONAL COOPERATIVE DRUG DISCOVERY GROUP FOR TREATMENT OF OPPORTUNISTIC INFECTIONS (NCDDG-OI)" must be typed in. Applications must be received by August 11, 1994.

These application forms may be obtained from the institution's office of sponsored research or its equivalent, and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

REVIEW CONSIDERATIONS

All applications will be judged on the basis of the scientific and technical merit of the proposed projects and the documented ability of the investigators to meet the RESEARCH OBJECTIVES of the RFA. Applications with first year total costs (direct and indirect) in excess of \$700,000 will be returned without review. Applications that are complete and responsive may be subjected to a triage by a peer review group to determine their scientific merit relative to other applications received. The NIAID will withdraw from competition those applications judged to be noncompetitive for award and will notify the Principal Investigator and institutional business official.

AWARD CRITERIA

Award criteria will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Barbara Laughon, Ph.D.
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C35
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 402-2304
FAX: (301) 401-3211

Direct inquiries regarding application preparation and review and address the letter of intent to:

Dianne Tingley, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C16
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0818
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Jane Unsworth
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B22
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075
FAX: (301) 480-3780

Schedule

Letter of Intent Receipt Date: July 15, 1994
Application Receipt Date: August 11, 1994
Scientific Review Date: November 1994
Advisory Council Date: February 1995
Anticipated Award Date: April/May 1995

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.856 - Microbiology and Infectious Diseases Research and No. 93.855 - Immunology, Allergic and Immunologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Parts 52 and 45 CFR Part 74 [and Part 92 when applicable for State and Local governments]. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH ON CLINICAL BIOETHICAL DILEMMAS

NIH GUIDE, Volume 23, Number 12, March 25, 1994

PA NUMBER: PA-94-051

P.T.

National Institute of Nursing Research

PURPOSE

The National Institute of Nursing Research (NINR) invites applications for grants to support research that will extend current knowledge about clinical bioethical dilemmas (and possible resolutions) that are faced by individuals and families. The goal of this program announcement is to generate research that will contribute knowledge of the ethical implications and actions arising from diagnostic and treatment strategies, in order to support those making decisions that impact their health and well-being and strengthen the quality and appropriateness of decisions made by family members.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Research on Clinical Bioethical Dilemmas, cross cuts all priority areas and relates directly to the responsibilities shared by individuals, families and practitioners for successfully implementing the priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit, public and private, organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Topics studied by foreign applications must have direct relevance to U.S. populations. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) award (R29). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms of support will be the National Institutes of Health individual research grant (R01) and FIRST award (R29). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Though the length of individual studies will vary, support will be provided for a period of up to five years, based on availability of funds and sufficient scientific progress. Applicants must plan for five years of support for the R29 award. Costs of individuals projects will vary. The average direct cost of an R01 award in FY 1993 was \$186,000. Direct costs for R29 awards are capped at \$100,000 in any one year and \$350,000 across all years.

RESEARCH OBJECTIVES

Rapidly occurring advancements in science and health care technology are generating new ethical issues with increasing frequency. The availability of health and illness related information is outpacing knowledge about the best strategies for assisting those who must use this information. Therefore, there is a growing need for strategies and frameworks

that can be used by health care professionals to organize and present clinical information in a way that is usefully supportive of the decision-making process that is required of patients and/or their families. These frameworks, when based on empirical studies of bioethical issues, should enable the determination of the best approaches for organizing information, deciding strategies, and facilitating individuals and their families in making clinical decisions. In the absence of such organizing frameworks, it is possible that when unstructured information is provided, it may actually work against the patient's needs and interests.

The NINR sponsored an interdisciplinary clinical bioethics workshop in 1989 as a means of exploring the research opportunities in bioethics and clinical practice. Proceedings from this workshop are available from NINR program staff listed under INQUIRIES. As a result of the recommendations made by workshop participants, NINR funded a small grants program from 1989 to 1991 focused on bioethics and clinical decision making research. The program was designed to support pilot and feasibility studies. This current Program Announcement builds on and expands that earlier research program on clinical bioethical issues.

Preserving a patient's individual autonomy has been a goal of national and institutional policies, as exemplified by "The Patient Self Determination Act," which was designed to involve patients actively in determining how much care they desire in order to maintain their life. From a policy perspective, involving patients directly in decisions about their own health and clinical care needs has both quality of life and economic imperatives. Advance directives are the means to formalize individual patients decisions about their future clinical care needs. Whether or not such advanced directives are useful and effective and actually protect an individual's autonomy still needs to be determined.

It is commonly assumed that knowledge is good, that knowing a diagnosis is better than not knowing. But if the new diagnostic capabilities only predict risk of developing diseases, will having this knowledge potentially cause more harm than good? Will the quality of life be diminished by having the information when nothing can be done to reduce the risk factors or have an impact on the outcome?

A central question concerns the optimum way to support people making decisions about therapeutic options when the long term effects of the treatments are not known. These issues become all the more challenging and complex when there is diminished autonomy due to development, such as with minors, or when understanding may be compromised, such as with some mental illnesses, certain disabilities, or mental retardation.

The NINR welcomes applications that propose empirical approaches to these ethical issues and dilemmas. Although it is expected that investigators will propose study designs that are appropriate to the research question being asked, it should be noted that both qualitative, quantitative, or combined approaches could be used.

Some examples of specific areas that may be pursued include, but are not limited to, the following:

1. Health-Related Decision Making Involving New Clinical Technologies. This area involves questions on how individuals make choices for their personal health when accepting or rejecting new diagnostic and therapeutic technologies, especially when some are still considered experimental. Factors such as psychological, sociocultural, economic, and quality of life issues that influence these decisions need to be examined. Determining which informational, educational, and counseling strategies are most effective in supporting autonomous decision making needs study. What is the influence of choices or the lack of choices when making these decisions? How do individuals respond and what factors are considered when decisions are being made about diagnostic tests that have greater or lesser degrees of uncertainty, sensitivity, or specificity? How do patients and families make decisions about new treatments such as surgical innovations or gene therapies? Do individuals and families consider costs when making these decisions for themselves; for others?

2. Patient Involvement in Clinical Decision Making. This area involves individuals who are receiving ongoing clinical care. The continuing evaluation of the appropriateness, efficacy, efficiency, and effectiveness of treatment and clinical intervention strategies, and the development of clinical practice standards or guidelines, are expected to influence how decisions about clinical care are made and how that care is provided. In addition, it is planned that such information will be made available to patients and their families in a form they can understand to assist them when making decisions about diagnostic, treatment and intervention strategies. Such patient-focused information will include information about clinical effectiveness, potential impact of treatments and intervention strategies on quality of life and cost data. To what extent is this new information available to and used by patients and their families? How patients and their families receive such information and how they respond to it is unknown. How decisions are made in light of this new clinical information needs to be determined. What factors related to psychological, sociocultural, economic and quality of life issues influence these decisions? How best can they be explored? Which informational, educational, or counseling strategies would be most effective in supporting autonomous decision making? Do such clinical factors as symptom intensity influence the outcome of decision making? To what extent? Are patients and their family members now more involved in clinical decision making? Do they make different decisions? To what extent do fiscal issues influence decisions, if at all?

3. Informed Consent in a Pluralistic Society. This area includes examining issues surrounding the informed consent process. Some questions that could be considered include: What factors influence decisions when "informed decisions" are made? Are individuals truly knowledgeable and well informed when they sign consent forms for clinical treatments? What ethnocultural influences play a role in informed decision making? What actually takes place when family members, or non-related members, of an ethnolinguistic group translate information about health status, or obtain consent for procedures or treatments? Who should be involved in obtaining consent when autonomy is diminished? What are the issues and best approaches to informed decision making for the developmentally disabled, children, adolescents, or adults with special needs?

4. Organ and Tissue Donation and Receipt. With increasing availability of transplantation and the ongoing need for organs and tissue, various strategies are used to obtain them. The influence of these strategies on individuals and families have not been fully explored. The aftermath of making a decision to donate either by an individual or a family member needs to be more fully understood. It has been recognized that there are cultural and ethnic differences in responding to organ and tissue donation, this results in some groups having little opportunity for receipt of a donation. These differences need to be examined. In addition, the need for transplantation, for example, of bone marrow, occurs during serious, life threatening illness. What factors influence decisions under these circumstances? Do these factors change over time or in association with complications, such as those occurring after transplantation? What strategies

are used to assist patients and families in the decision making process, during treatment, and after treatment? How specific and how much information is provided?

5. Privacy and Confidentiality. This area involves examining such issues as how best to protect the privacy of individuals, who now have access to information about themselves or about other members of their families, that has been previously unavailable. What factors are involved in protecting the confidentiality of information about an individual when it may be important and relevant to other members of the family or community? Increasing amounts of information are available about individuals and their health status in clinical databases and other potentially accessible sources. What strategies are effective in protecting individual privacy under these circumstances?

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

(NOTE: When the proposed study or studies in the RFA or PA involves a gender specific study or a single or limited number of minority population groups, this should also be stated to inform potential applicants and reviewers.)

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are also found in the PHS 398 (rev. 9/91) instructions. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application. Applicants for FIRST awards should note that three letters of reference must be submitted with the application.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892***

REVIEW CONSIDERATIONS

Applications received under this program announcement will be assigned to an initial review group on the basis of established Public Health Service referral guidelines. The IRG will review the applications for scientific and technical merit in accordance with the standard NIH peer review procedures. Applications recommended for further consideration will receive a second-level review by the appropriate national advisory council. Only applications recommended by the Council/Board may be considered for funding.

AWARD CRITERIA

Applications recommended for further consideration will be considered for available funds on the basis of the scientific and technical quality of the proposed project determined by peer review, program needs and balance, policy considerations, and availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

To receive a copy of "Bioethics and Clinical Practice: Examining Research Outcomes and Methods," direct inquiries to:

Office of Information and Legislative Affairs
National Institute of Nursing Research
Building 31, Room 5B13
Bethesda, MD 20892
Telephone: (301) 496-0207

Direct inquiries regarding scientific programmatic issues to:

Dr. Patricia Moritz
Nursing Systems Branch
National Institute of Nursing Research
Westwood Building, Room 738
Bethesda, MD 20892
Telephone: (301) 594-7493

Direct inquiries regarding fiscal matters to:

Ms. Sally A. Nichols
Grants Management Office
National Institute of Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 594-7498

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.361, Nursing Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

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Bethesda, MD 20816***

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Vol. 23, No. 13
April 1, 1994

RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

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NOTICES OF AVAILABILITY (RFPs AND RFAs)

EVALUATION OF CHEMOPREVENTIVE AGENTS BY IN VIVO SCREENING ASSAYS

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFP AVAILABLE: NCI-CN-45000-46

P.T.

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Prevention and Control, Chemoprevention Branch, wishes to award Master Agreement (MA) contracts for the evaluation of chemopreventive agents by in vivo screening assays. The required services will be defined by Master Agreement Orders (MAO) issued during the four year period of performance. This solicitation is the annual announcement to expand the current pool of MA Holders qualified to perform this type of work. All interested offerors must submit proposals to be eligible to compete for future MAO RFPs. Pursuant to the MAO the Contractor will conduct in vivo screening studies in small rodents using gavage and other routes of administration to administer the designated chemopreventive agents in animal models using any carcinogenic mechanism (that is consistent with the Evaluation Criteria), such as the administration of carcinogens, promoters, hormones, irradiation, cells or

other carcinogenic agents. Agents to be tested are potentially hazardous. The animal model systems also involve the use of carcinogens. Laboratory practices that keep any element of risk to personnel at an absolute minimum will be employed. Where indicated, tissue and compound handling must be performed in (at least) Class I laminar flow agents. It is required that the animal facilities be maintained in accordance with the NIH Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act as administered by the USDA, and the U.S. Government Principals for Utilization and Care of Vertebrate Animals Used for Testing Research and Training. This research will be performed under cost reimbursement and/or fixed price MAO's. The contractor must have all the equipment necessary to accomplish the studies including, but not limited to, animal racks and caging, hazardous chemical storage cabinets and refrigerators, pathology equipment such as microscopes and microtomes and miscellaneous laboratory equipment. The laboratory must have or have access to appropriate terminal and computer facilities and equipment for data collection and storage. It is estimated that four to five Task Orders per year will be issued pursuant to the Master Agreement contracts. The Master Agreement Announcement will be available on approximately March 25, 1994. Proposal due date will be approximately May 24, 1994.

INQUIRIES

Copies of the MAA/RFP NCI-CN-45000-46 may be obtained by sending a written request to:

Mr. Schuyler T. Eldridge
Research Contracts Branch
National Cancer Institute
Executive Plaza South, Suite 635,
Bethesda, MD 20892
Telephone: (301) 496-8603

Collect calls will not be accepted.

DETERMINATION OF SERUM ANTIBODIES TO PERIODONTAL PATHOGENS IN THE U.S. POPULATION

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFP AVAILABLE: NIH-NIDR-2-94-7R

P.T.

National Institute of Dental Research

The National Institute of Dental Research (NIDR) has a requirement for a state-licensed microbiology laboratory capable of processing thousands of serum samples for antibodies to periodontal pathogens, including the capability of receiving and transporting the samples. The objective of this study is to determine the occurrence of elevated serum antibodies to periodontal pathogens in a sample of persons examined in the Third National Health and Nutrition Examination Survey (NHANES III). Serum from the NHANES III subjects has already been collected, frozen, and stored for further analysis. The serum must be assayed by ELISA procedures.

Request for Proposals (RFP) NIH-NIDR-2-94-7R will be available on or about April 12, 1994, with proposals due May 12, 1994. It is anticipated that one award will be made as a result of this solicitation.

INQUIRIES

The RFP package is available by written request to:

Marilyn R. Zuckerman
Contract Management Office
National Institute of Dental Research
Westwood Building, Room 533
Bethesda, MD 20892

BREAST CANCER EDUCATION INITIATIVES

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFA AVAILABLE: CA-94-011

P.T.

National Cancer Institute

Letter of Intent Receipt Date: May 2, 1994
Application Receipt Date: June 16, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Cancer Institute (NCI) invites grant applications to create new educational programs aimed at reducing the mortality and morbidity of breast cancer. These cancer education programs are intended to disseminate what is professionally known about the prevention, early detection, and treatment of breast cancer to primary care physicians, other health professionals, and the lay community with special attention to minority or underserved populations.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Breast Cancer Education Initiatives, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, Cancer Centers, hospitals, Laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support for this program will be through the NCI Cancer Education (R25) Award. This is a flexible, curriculum-driven program aimed at developing and sustaining innovative and, possibly, unique educational approaches that ultimately will have an impact on reducing cancer incidence, mortality, and morbidity, as well as on improving the quality-of-life of cancer patients. The current guidelines for the Cancer Education Program (R25) may be obtained from the program director listed under INQUIRIES.

Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed three years. It is anticipated that the average amount of direct costs awarded per grant will range from \$50,000 to \$130,000 depending upon the proposed program. Indirect costs will be allowed at the rate of eight percent of total direct costs (exclusive of equipment). The earliest feasible start date for the initial award will be September 1994.

This RFA is a one-time solicitation. Future competitive continuation applications will compete with all other applications in the Cancer Education Grant Program (R25). However, if the NCI determines that there is a sufficient program need, a new request for competitive continuation and/or new applications will be announced.

FUNDS AVAILABLE

For FY 1994, \$1,600,000 in total costs will be available for, it is estimated, some 15 to 20 awards. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. A greater or lesser amount of dollars and number of awards may be negotiated based on the quality of the applications and the availability of funds.

RESEARCH OBJECTIVES

The purpose of this RFA is to stimulate breast cancer educational programs among health professionals and the lay public. The NCI proposes that Cancer Centers and other organizations with appropriate breast cancer expertise collaborate with educational specialists and other professional and lay groups, particularly those with access to underserved populations, to design and implement programs dealing with one or more of the following target populations for this initiative: primary care physicians, health professional faculty, health professional students, women's groups, minority or underserved groups, employer-based groups, breast cancer patients and their families. The NCI also strongly encourages submission of applications from minority health professional schools and from other organizations that have traditionally served minority communities and geographically isolated populations.

SPECIAL REQUIREMENTS

If several institutions are jointly involved or if several departments within an institution are cooperating in this RFA, a special, central, interdisciplinary Cancer Education Committee consisting of members from the collaborating organizations should be in place. The functions of the Committee would be to provide effective monitoring and coordination of the program.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 2, 1994, a letter of intent that includes a descriptive title of the proposed educational proposal, the name, address, and telephone number of the Principal Investigator/Educator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Robert C. Adams at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NCI Program Director listed under INQUIRIES.

Applications must be received by June 16, 1994.

REVIEW CONSIDERATIONS

Applications will be reviewed by an appropriate review group convened by the Division of Extramural Activities, NCI. Consult the RFA for additional details.

AWARD CRITERIA

The anticipated date of award is September, 1994. Awards will be made according to priority score, availability of funds, and programmatic priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Robert C. Adams
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Room 520
Bethesda, MD 20892
Telephone: (301) 496-8580
FAX: (301) 402-4472

Direct inquiries regarding grants management issues to:

Mr. Robert Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.398, Cancer Research Manpower. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A, Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285 and administered under HHS regulations and PHS grant policies.

HOSPICE AND PALLIATIVE CARE EDUCATION PROGRAMS

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFA AVAILABLE: CA-94-012

P.T.

National Cancer Institute

Letter of Intent Receipt Date: May 2, 1994
Application Receipt Date: June 16, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Cancer Institute (NCI) invites grant applications to create new educational programs to address health professional training in palliative patient care. The intent of this RFA is to emphasize NCI's concern for this neglected area with the expectation that any funded programs will act as catalysts to encourage further interest and development in the medical community.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Hospice and Palliative Care Education Programs, is related to the priority area of Educational and Community-based Programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, cancer centers, hospitals, hospices, units of State and local governments, and eligible agencies of the Federal government. Foreign organizations are not eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Support for this effort will be through the NCI Cancer Education (R25) Award. This is a flexible, curriculum-driven program aimed at developing and sustaining innovative and, possibly, unique educational approaches that ultimately will have an impact on reducing cancer incidence, mortality, and morbidity, as well as on improving the quality-of-life of

cancer patients and their families. The current guidelines for the Cancer Education Program (R25) may be obtained from the program director listed under INQUIRIES.

Applicants will be responsible for the planning, direction, and execution of the proposed project. The total project period for applications submitted in response to this RFA may not exceed three years. The earliest feasible start date for the initial award will be September 1994. It is anticipated that the average amount of direct costs awarded per grant will range from \$50,000 to \$100,000 depending upon the proposed program. Indirect costs will be allowed at the rate of eight percent of total direct costs (exclusive of equipment).

This RFA is a one-time solicitation. Future competitive continuation applications will compete with all other applications in the Cancer Education Grant Program (R25). However, if the NCI determines that there is a sufficient program need, a new request for competitive continuation and/or new applications will be announced.

FUNDS AVAILABLE

For FY 1994, \$500,000 in total costs will be available for, it is estimated, some five to seven awards. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. A greater or lesser amount of dollars and number of awards may be negotiated based on the quality of the applications and the availability of funds.

RESEARCH OBJECTIVES

This RFA proposes to stimulate medical schools, schools of nursing, cancer centers, oncology divisions, and other health professional entities to design methodologies for the education and training of health care professionals in hospice and palliative care. Hospices, either individually or in regional settings in collaborative arrangements with other medical centers are particularly encouraged to submit applications in response to this RFA.

The NCI hopes to stimulate multi-disciplinary, team approaches to palliative care by encouraging a variety of educational programs aimed at medical students, physicians, other health professionals, and hospice personnel. The ultimate goal is to benefit cancer patients and their families.

SPECIAL REQUIREMENTS

If several institutions are jointly involved or if several departments within an institution are cooperating in this RFA, a special, central, interdisciplinary Cancer Education Committee consisting of members from the collaborating organizations or units should be in place. The functions of the Committee would be to provide effective monitoring and coordination of the program.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 2, 1994, a letter of intent that includes a descriptive title of the proposed educational proposal, the name, address, and telephone number of the Principal Investigator/Educator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Robert C. Adams at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248; and from the NCI Program Director listed under INQUIRIES.

Applications must be received by June 16, 1994.

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. Consult the RFA for additional details.

AWARD CRITERIA

The anticipated date of award is September, 1994. Awards will be made according to priority score, availability of funds, and programmatic priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Dr. Robert C. Adams
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Room 520
Bethesda, MD 20892
Telephone: (301) 496-8580
FAX: (301) 402-4472

Direct inquiries regarding grants management matters to:

Mr. Robert Hawkins
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Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.398, Cancer Research Manpower. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A, Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285 and administered under HHS regulations and PHS grant policies.

BASIC OSTEOPOROSIS NEW EXPERIMENTAL STRATEGIES

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFA AVAILABLE: AR-94-005

P.T.

National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Aging

Letter of Intent Receipt Date: June 28, 1994

Application Receipt Date: July 26, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Bone Biology and Bone Diseases Branch of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the Bone and Mineral Research Program of the Endocrinology Research Section of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the Geriatrics and Biology of Aging Programs of the National Institute on Aging (NIA) invite investigator-initiated research project grant applications to encourage and facilitate research projects designed to develop promising basic cellular, molecular, physiological, and genetic approaches to osteoporosis.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Basic Osteoporosis New Experimental Strategies, is related to the priority areas of diabetes and chronic disabling conditions and older adults and preventive services. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from women and minority individuals are encouraged.

MECHANISM OF SUPPORT

Support for this program will be through investigator-initiated research grant applications (R01) and FIRST (R29) awards. This RFA is a one-time solicitation for fiscal year 1995. The total project period for applications submitted in response to the present RFA may not exceed four years. FIRST (R29) awards must be for five years. The anticipated award date is April 1, 1995.

FUNDS AVAILABLE

Approximately \$2,000,000 in total costs per year for four years will be committed by the NIAMS to fund applications submitted in response to this RFA. An additional \$500,000 will be committed by the NIDDK, and an additional \$600,000 by the NIA. The direct cost of each R01 project is limited to \$160,000 for the first year and each R29 is ---. Thus it is anticipated that a total of 12 to 14 projects will be funded in FY 95.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or Principal Investigator should be included with the application.

RESEARCH OBJECTIVES

Effective approaches to the treatment of established osteoporosis are urgently needed. Such new therapeutic approaches are most likely to arise from improved understanding of the basic biology of bone growth and maintenance.

In order to capitalize on current scientific opportunities, it is necessary to integrate biological insights and methodologies from a broad range of specialties. The overall goal of the BONES initiative is to encourage and support new basic research in the areas of bone structure, formation, remodeling, and repair. This initiative is designed to (1) encourage established bone biology investigators to address osteoporosis-related problems with novel approaches and the most powerful methodologies available; (2) increase the pool of investigators working in osteoporosis-related basic science areas by drawing researchers from genetics, cell and molecular biology, and structural chemistry into bone research; and (3) foster the development of interactions between laboratories originating in different disciplines.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 28, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

The letter of intent is to be sent to Dr. William Sharrock at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this RFA. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/ 594-7248; and from the program staff listed under INQUIRIES. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy Broadwater
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 406
Bethesda, MD 20892
Telephone: (301) 594-9979
FAX: (301) 594-9673

Applications must be received by July 26, 1994.

REVIEW CONSIDERATIONS

Applications may be triaged by an NIAMS peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIAMS. The second level of review will be provided by the NIAMS, NIDDK, and NIA advisory councils.

Review criteria for RFAs are generally the same as those for unsolicited research grant applications.

AWARD CRITERIA

The anticipated date of award is April 1, 1995. In addition to the technical merit of the application as reflected in the priority score, the NIAMS, NIDDK, and NIA will consider how well the applicant institution meets the goals and objectives of the program as described in the RFA, availability of resources and/or study populations.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

William Sharrock, Ph.D.
Bone Biology and Bone Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 594-9975
FAX: (301) 594-9673

Ronald Margolis, Ph.D.
Endocrinology Research Section
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 594-7549
FAX: (301) 594-9011

Sherry Sherman, Ph.D.
Geriatrics Program
National Institute on Aging
Gateway Building, Suite 2C218
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-9322
FAX: (301) 402-2945

Direct inquiries regarding fiscal matters to:

G. Carol Fitzpatrick
Grants Management Office
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 722A
Bethesda, MD 20892
Telephone: (301) 594-9974
FAX: (301) 594-9950

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.846, 93.847, and 93.866. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241 and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SPECIALIZED CENTERS OF RESEARCH: TRANSFUSION BIOLOGY AND MEDICINE

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFA AVAILABLE: HL-94-012

P.T.

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: May 31, 1994
Application Receipt Date: September 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF THE APPLICATION, FROM THE CONTACT LISTED IN THE "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The objectives of the Specialized Centers of Research (SCOR) program in Transfusion Biology and Medicine are to improve the safety and efficacy of blood and blood components, define the indications for their use, evaluate and possibly modify immunological responsiveness following their administration, and develop and evaluate alternative treatment strategies that substitute for certain of their functions or stimulate their endogenous production so as to reduce transfusion needs. This initiative also encourages the use of new and innovative technologies to pursue fundamental research studies in transfusion biology and clinical investigations in transfusion medicine. The goals of this program are to understand better the basic biology of transfusion; make optimal use of blood, blood components, and plasma protein derivatives in specific replacement therapy; improve transfusion practice; and perform basic and applied research on blood substitutes.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Centers of Research in Transfusion Biology and Medicine, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit domestic institutions, public and private, such as universities, colleges, hospitals, and laboratories. Awards will not be made to foreign institutions. However, under exceptional circumstances, a foreign component critical to a project may be included as a part of that project. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Heart, Lung, and Blood Institute (NHLBI) SCOR (P50) grant to support this research program. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

Basic and Clinical Research

It is essential that all applications include both basic and clinical research. Interactions between basic and clinical scientists are expected to strengthen the research, enhance transfer of fundamental research findings to the clinical setting, and identify new research directions. Applications that include only basic or only clinical research will not be responsive to this RFA. In addition, clinical research projects focused on large epidemiologic studies or large clinical trials will be considered unresponsive to this RFA.

FUNDS AVAILABLE

Up to \$1,125,000 in direct costs, not including indirect costs for collaborating institutions, in the first year with a maximum increase of no more than four percent in each additional year may be requested in each application. Award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that at least two SCOR grants will be funded. NHLBI's FY 1996 plans for this initiative include a maximum of \$4.4 million. The specific amount to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds.

RESEARCH OBJECTIVES

Background

During the past decade, significant scientific advances have been made in transfusion medicine that have improved the safety and quality of blood, blood components and plasma derivatives and have changed transfusion practices. Advances have been made in detecting evidence of viral pathogens such as HIV-1, HIV-2, HTLV-I/HTLV-II and hepatitis C in donated blood, thus preventing such agents from entering the blood supply. Moreover, procedures have been developed to inactivate viruses in plasma derivatives and soon in plasma itself. Improved apheresis technologies have been developed that permit more efficient collection and manipulation of blood components and bone marrow. Investigators have described properties of newly developed plasma derivatives. Techniques have been developed that may lead to the use of stem cells from umbilical cord blood for bone marrow transplantation. As a result, the importance of blood transfusion has been greatly expanded through the use of components and derivatives in increasingly specialized and effective forms of therapy.

The use of blood and blood components continues to increase. Improved patient care, including aggressive cancer chemotherapy programs, bone marrow transplantation and sophisticated cardiac surgery procedures have contributed heavily to this growth which is expected to continue into the future. Consequently, the implementation of research programs to determine the optimal use of this valuable resource is important and timely.

Proposed Research

The principal research aim of this RFA is to encourage basic and clinical research towards the optimal use and improvement of transfusion therapy. Recent progress in our understanding in such areas as immune regulation and hematopoiesis make this an opportune time to encourage research in the following areas of emphasis: (1) immunomodulatory aspects of transfusion; (2) development of novel cell therapies and cytokine therapies; (3) structure/function relationships of human blood cell surface antigens; (4) blood substitutes; and (5) indications for red cell or platelet transfusion.

The topics may address one or more than one area of emphasis. For example, it would be appropriate for a SCOR applicant to propose projects that address research issues pertaining to one area of interest such as structure/function relationships of human blood cell surface antigens or a combination such as structure/function relationships of human blood cell surface antigens and immunomodulatory aspects of transfusion. Applicants should also note that a SCOR program must meet the following criteria: (1) address areas of significant national need and clinical importance; (2) attract talented investigators who foster the development of a multidisciplinary and collaborative synergistic approach; (3) include both basic and clinical components; and, most importantly; (4) have the potential to accelerate the transfer of basic research to clinical application.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the principal investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 557A
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications will be judged on the basis of the scientific and technical merit of the proposed research; the qualifications and research experience of the investigators; the collaborative interaction among basic and clinical research components; the adequacy of the environment; and the appropriateness of the budget.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Applications must be received by September 15, 1994

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify issues or questions from potential applicants are welcome.

Direct inquiries regarding scientific issues and requests for the RFA to:

George J. Nemo, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 504
Bethesda, MD 20892
Telephone: (301) 496-1537
FAX: (301) 402-4843

Direct inquiries regarding fiscal and administrative matters to:

Ms. Jane Davis
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 594-7436
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

The programs of the Division of Blood Diseases and Resources, NHLBI, are described in the Catalog of Federal Domestic Assistance No. 93.839. Awards will be made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or Health Systems Agency review. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

SPECIALIZED CENTERS OF RESEARCH: HEMOSTATIC AND THROMBOTIC DISEASES

NIH GUIDE, Volume 23, Number 13, April 1, 1994

RFA AVAILABLE: HL-94-013

P.T.

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: May 31, 1994
Application Receipt Date: September 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF THE APPLICATION, FROM THE CONTACT LISTED IN THE "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The objectives of the Specialized Centers of Research (SCOR) program in Hemostatic and Thrombotic Diseases are to improve the basic understanding of the processes involved in hemostasis and thrombosis and to encourage the application of this fundamental knowledge to clinical situations. This initiative emphasizes the use of new and innovative technology to provide better insight and develop treatment for thrombosis and related cardiovascular disorders that are the leading cause of death in the United States.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Centers of Research in Hemostatic and Thrombotic Diseases, is related to the priority area of blood diseases and resources. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit domestic institutions, public and private, such as universities, colleges, hospitals, and laboratories. Awards will not be made to foreign institutions. However, under exceptional circumstances, a foreign component critical to a project may be included as a part of that project. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Heart, Lung, and Blood Institute (NHLBI) SCOR (P50) grant to support this research program. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

Basic and Clinical Research

It is essential that all applications include both basic and clinical research projects. Interactions between basic and clinical scientists are expected to strengthen the research, enhance transfer of fundamental research findings to the clinical setting, and identify new research directions.

Applications that include only basic or only clinical research will not be responsive to this RFA. In addition, clinical research projects focused on large epidemiologic studies or large clinical trials will be considered unresponsive to this RFA.

FUNDS AVAILABLE

Up to \$1,125,000 in direct costs, not including indirect costs for collaborating institutions, in the first year with a maximum increase of no more than four percent in each additional year may be requested in each application. Award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that at least two new SCOR grants will be funded. NHLBI's FY 1996 plans for this initiative include a maximum of \$4.4 million. The specific amount to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds.

RESEARCH OBJECTIVES

Background

Thrombosis and related cardiovascular diseases are the leading cause of death in the US. The progress made in thrombosis research has revealed a complex and dynamic balance between the thrombotic and fibrinolytic systems. Major new advances have put us on the threshold of fundamental understanding of the cellular and surface processes involved in modulating thrombotic and fibrinolytic pathways. Understanding the biology of endothelial cells is still in its infancy and a deeper insight into this area may lead to major therapeutic advances. New understandings in molecular genetics is likely to make gene therapy of bleeding disorders a reality. Progress is being made in the knowledge of how megakaryocytes grow and differentiate and what controls platelet production. With identification of growth factors that control these processes, the day may not be too far away when circulating levels of platelets may be regulated and the devastating consequences of neonatal thrombocytopenia avoided. There is a need to continue this research progress and put special

emphasis on applying these basic research accomplishments to clinical situations. The overall goal of this program is to support quality basic research, facilitate transfer of the basic knowledge to the bed side and stimulate clinical studies in hemostatic and thrombotic diseases. Such a program will require an intimate interface between basic and clinical research that cannot be accomplished by other means of support provided by NHLBI. It becomes essential then that all SCOR applications must contain major clinical components. Other factors such as research programs complementary to thrombosis area, institutional training programs, training experience of the SCOR director and other key staff will be considered important for the enrichment of the scientific environment under which mutual information exchange may flourish.

Proposed Research

The principal aim of this RFA is to encourage basic and clinical research towards the improvement of prevention/therapy of hemostatic and thrombotic diseases. Recent progress in the understanding of gene regulation and identification of anticoagulant factors make this an opportune time to encourage research in the following areas of emphasis: (1) risk factors for thrombosis; (2) influence of nutritional elements and environmental factors on hemostatic and thrombotic disease; (3) diagnosis, assay, and treatment for venous thrombosis; (4) regulation of adhesive proteins and processes; and (5) synthesis, catabolism and function of fibrinolytic proteins.

The topics may address one or more than one area of emphasis. Applicants should also note that a SCOR program must meet the following criteria: (1) address areas of significant national need and clinical importance; (2) attract talented investigators who foster the development of a multidisciplinary and collaborative synergistic approach; (3) include both basic and clinical components; and, most importantly; (4) have the potential to accelerate the transfer of basic research to clinical application. Applicants may use their own imagination within the SCOR guidelines.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the principal investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 557A
Bethesda, MD 20892

REVIEW CONSIDERATIONS

Applications will be judged on the basis of the scientific and technical merit of the proposed research; the qualifications and research experience of the investigators; the collaborative interaction among basic and clinical research components; the adequacy of the environment; and the appropriateness of the budget. See RFA for additional information.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Applications must be received by September 15, 1994.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify issues or questions from potential applicants are welcome.

Direct inquiries regarding scientific issues and requests for the RFA to:

Pankaj Ganguly, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
Federal Building, Room 5C14
Bethesda, MD 20892
Telephone: (301) 402-2237
FAX: (301) 496-9940

Direct inquiries regarding fiscal and administrative matters to:

Ms. Jane Davis
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 594-7436
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.839. Awards will be made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or Health Systems Agency review. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

ONGOING PROGRAM ANNOUNCEMENTS

AGING AND BONE QUALITY

NIH GUIDE, Volume 23, Number 13, April 1, 1994

PA NUMBER: PA-94-052

P.T.

National Institute on Aging
National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE

The National Institute on Aging (NIA) and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invite research applications to elucidate the nature and consequences of age-related changes in bone quality and the relationship of these changes to enhanced bone fragility and susceptibility to osteoporotic fractures. Factors that contribute to bone quality include architecture, density and mechanical strength.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement (PA), Aging and Bone Quality, addresses the priority area of osteoporosis. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, non-profit and for-profit organizations, private and public such as colleges, universities, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) awards (R29). Applications from minorities and women are encouraged.

MECHANISM OF SUPPORT

Support for this program will be by the research project grant (R01) and the FIRST (R29) award.

RESEARCH OBJECTIVES

Background

The progressive loss of bone with age very commonly leads to osteoporosis, a condition characterized by increased skeletal fragility and susceptibility to fracture. Osteoporosis and its consequences are a significant cause of frailty, morbidity, and even mortality. However, while in older individuals reduced bone mass is important both in contributing to and predicting an enhanced risk of fracture, low bone mass alone is not a sufficient explanation for osteoporotic fractures. This is exemplified by the substantial overlap in bone density between normal individuals and patients who sustain hip and other osteoporotic fractures. A new perspective is needed that broadens the conceptual basis of skeletal integrity to include in addition to bone mass, qualitative factors that may impact on bone strength such as geometry, macro and micro-structural organization, distribution of material within bone, biochemical composition, and the burden of unrepaired microdamage.

An NIA Workshop on Aging and Bone Quality, held September 3-4, 1992, underscored the need to study bone quality and identified promising new areas of research, which can be found in the workshop Proceedings in Calcified Tissue International, Supplement 1, (53), 1993. This PA reflects the priority areas that were identified at the workshop.

This PA is directed towards: (1) stimulating research aimed at elucidating age-related mechanisms that influence the development and/or course of osteoporosis and (2) developing strategies aimed at preventing or lessening the burden of osteoporosis-related fractures in older individuals. Specifically, this PA seeks applications for basic and clinical research to identify and evaluate the effects of age on factors related to bone quality and/or strategies to modify the impact of these factors on skeletal fragility and increased fracture susceptibility. Topics of interest include, but

are not limited to:

- o Age-related changes in architecture, mechanical properties, and strength of bone
- o Evaluation of changes in bone matrix and mineralization and their impact on strength and resistance to microdamage
- o Assessment of the consequences of age on the accumulation of cortical and trabecular microdamage and their relationship to bone strength and fracture biomechanics
- o Age-related changes in the detection of microdamage and activation, and initiation of the remodelling and repair processes in bone
- o Determination of age- and disease-related changes in biochemical, cellular, and structural factors affecting bone quality
- o Elucidation of the role and function of osteocytes and bone lining cells in bone metabolism
- o The nature of changes in osteocyte viability and function with age and the effect of these changes on the structural and mechanical properties of bone
- o Development of model systems that reflect normal physical and physiological aspects related to functional loading and responses to loading in aged bone
- o Development and application of techniques such as histomorphometry, ultrasound, NMR, and QCT to evaluate changes in architecture, bone strength and fracture susceptibility

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on the application form PHS 398 (rev. 9/91) available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248. Applications will be accepted on the standard application receipt dates as indicated in the application kit. The program announcement title and number must be typed on line 2a of the face page.

FIRST (R29) award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the standard NIH peer review procedures. Following scientific-technical review, applications recommended for further consideration will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds on the basis of scientific merit, program balance among research areas of the announcement, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Chhanda Dutta, Ph.D.
Geriatrics Program
National Institute on Aging
Gateway Building, Suite 3E327
Bethesda, MD 20892
Telephone: (301) 496-1033

Joan A. McGowan, Ph.D.
Bone Biology and Bone Diseases Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 594-9957



Direct inquiries regarding fiscal matters to:

Joanne Colbert
Grants and Contracts Management Office
National Institute on Aging
Gateway Building, Room 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410), as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to the Health Systems Agency review. Awards will be administered under PHS grants policy as stated in the PHS Grants policy statement, DHHS Publication NO. (OASH) 90-50,000, revised October 1, 1990.

ADDENDUM

GRANT WRITING WORKSHOP FOR NUTRITION FOR PROGRAM ANNOUNCEMENT PA-94-033

NIH GUIDE, Volume 23, Number 13, April 1, 1994

P.T. 34; K.W. 0710095, 1014006

National Cancer Institute

The following addendum is added to the notice that appeared in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994:

"For persons who are unable to attend, a transcript of the meeting will be made available, and may be obtained by contacting:

Dr. Jacqueline Whitted
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 232
Bethesda, MD 20892
Telephone: (301) 496-8584
FAX: (301) 496-8675

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 14
April 8, 1994

RICHARD W MURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details

The Public Health Service (PHS) strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the american people.

NOTICES

NICHD TRANSGENIC MOUSE DEVELOPMENT FACILITY

NIH GUIDE, Volume 23, Number 14, April 8, 1994

P.T.

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) Transgenic Mouse Development Facility (NTDF) is a research resource that develops transgenic mice for investigators requiring these services. It was established to provide reliable and affordable transgenic mice primarily to biomedical research grantees.

Specifically, the NTDF supports basic biomedical research by providing investigators with the following customized services:

- o Analyzing constructs for microinjection.
- o Microinjecting constructs into fertilized one-cell mouse eggs and reimplanting into pseudopregnant recipient females.
- o Testing potential founders for DNA integration.
- o Producing at least two integration-positive transgenic mice.
- o Fast turnaround time (12-14 weeks)

Applications for services should be requested from the Director, NTDF. Completed applications may be submitted anytime to the NICHD Project Officer for review. Review is completed within two weeks of receipt. All applications are handled confidentially and those constructs approved are microinjected at the NTDF. The Investigator is charged a non-refundable fee of \$500 per construct for initial analysis. An additional fee of \$1500 per construct is assessed if two or more integration-positive transgenic mice are produced.

The NTDF is supported by a contract award from the National Institute of Child Health and Human Development, NIH.

INQUIRIES

Direct programmatic inquiries regarding this research resource to:

Allan Lock, D.V.M.
NTDF Project Officer
National Institute of Child Health and Human Development
Building 6100, Room 4B01
Bethesda, MD 20892
Telephone: (301) 496-5541

Direct requests for applications and resource inquiries to:

Mark Swanson, Ph.D. or Mr. Frederick Huntress
NICHD Transgenic Mouse Development Facility
303B College Road East
Princeton, NJ 08540
Telephone: (609) 520-0300, Ext. 183
FAX: (609) 520-9864

POLICY STATEMENT REGARDING SITE VISITS BY THE NIDR

NIH GUIDE, Volume 23, Number 14, April 8, 1994

P.T.

National Institute of Dental Research

The National Institute of Dental Research (NIDR) announces a modification in review procedures used for program project (P01) applications and other large granting mechanisms such as Phase II Small Business Innovation Research (SBIR) applications (R44).

The NIDR will eliminate site visits as a regular feature in the review of these applications. Until further notice P01 and R44 applications will be reviewed by ad hoc groups of subject matter experts by mechanisms other than site visit. The basis for the judgement of scientific merit in most instances will be solely the written application submitted by the applicant. However, in some instances the reviewers may request additional information in writing, by teleconference, or by means of an applicant interview.

INQUIRIES

Inquiries regarding this policy may be directed to:

H. George Hausch, Ph.D.
Extramural Programs
National Institute of Dental Research
Westwood Building, Room 519
Bethesda, MD 20892
Telephone: (301) 594-7632

NOTICES OF AVAILABILITY (RFPs AND RFAs)

EVALUATION OF ISCHEMIC HEART DISEASE IN WOMEN - CLINICAL CENTERS

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFP AVAILABLE: NHLBI-HC-94-13

P.T.

National Heart, Lung, and Blood Institute

This announcement revises the issue and response dates, the award date, and the number of anticipated awards for Request for Proposals (RFP) No. NHLBI-HC-94-13 published in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994. RFP NHLBI-HC-94-13 is now available and proposals are due on June 30, 1994. Three to five awards are anticipated to be made in March 1995.

The National Heart, Lung, and Blood Institute (NHLBI) requires three to five clinical centers to evaluate innovative diagnostic methods that will improve the diagnostic reliability of cardiovascular testing in evaluation of ischemic heart disease in women. Innovative approaches proposed in evaluation of myocardial ischemia should include physiologic or functional measurements such as impaired metabolism, perfusion, or endothelial function as well as assessment of epicardial coronary arteries by angiography. Each clinical center will be fully independent and expected to fulfill all the requirements outlined in this RFP. The clinical centers will evaluate diagnostic methods and perform common study protocols, including angiography, on 100 participants annually for three years. The anticipated period of performance is from March 1, 1994 through February 28, 1999.

INQUIRIES

For a copy of the RFP send a written request, citing RFP No. NHLBI-HC-94-13, to:

Donna J. Neal
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 3C16
7550 Wisconsin Avenue
Bethesda, MD 20892

PROSPECTIVE STUDY DRUG USE NETWORKS/HIV

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFP AVAILABLE: N01DA-4-6401

P.T.

National Institute on Drug Abuse

The National Institute on Drug Abuse (NIDA) is soliciting proposals from qualified organizations to conduct research related to HIV risk networks of drug injectors and their sexual and drug use partners. Such analysis will require prospective ethnographic and epidemiologic HIV-related research that includes field observations, interviews, behavioral surveys, and HIV testing in at least two communities. The objectives are to access and study networks of drug injectors and sexual partners whose members are at risk for HIV transmission due to their drug-based and/or sex-based contacts. This research will require university research teams, local health departments, and possibly community agencies to work collaboratively in the planning and implementation of the proposed project.

It is estimated that a three-year, cost-reimbursement contract will result from this requirement. The estimated issuance date for RFP No. N01DA-4-6104 is April 7, 1994, and responses are due to be received in the Contracting Office forty-five calendar days thereafter.

INQUIRIES

Requests for copies of solicitations will be honored if received within 30 calendar days after issuance of the solicitation. Requests received after this period will be filled on a first-come, first-served basis until the supply is exhausted; however, there is no assurance that copies requested after the 30th day will reach the requestor before the due date for receipt of responses. This requirement represents a new effort. All reasonable sources may submit a proposal that will be considered by the Agency. Only written or FAX requests for this RFP will be accepted.

Written requests are to be forwarded to:

Patricia W. Mummaugh
Contracts Management Branch
National Institute on Drug Abuse
Parklawn Building, Room 10-49
5600 Fishers Lane
Rockville, MD 20857
FAX: (301) 443-7595

This announcement does not commit the Government to make an award.

CLINICAL SITE MONITORING

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFP AVAILABLE: NIH-NIAID-DAIDS-95-06

P.T.

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) has a requirement to establish and maintain a Clinical Site Monitoring Group for on-site monitoring of the Division of AIDS-sponsored Adult and Pediatric AIDS Clinical Trials Group (ACTG) and the Community Programs for Clinical Research on AIDS (CPCRA) sites. This is a recompetition of an ongoing project awarded under contract N01-AI-05081 to Pharmaceutical Product Development, Inc. The purpose of this five-year Clinical Site Monitoring Contract is to administer a system for monitoring of DAIDS-funded ACTG and CPCRA sites, and conduct educational and training activities for the site monitors and personnel at the clinical sites.

This is an announcement for an anticipated Request for Proposal (RFP). RFP No. NIH-NIAID-DAIDS-95-06 will be issued on or about April 21, 1994 with a closing date tentatively set for June 21, 1994.

INQUIRIES

To receive a copy of the RFP, provide this office with three self-addressed mailing labels. A short version of the RFP will be provided first, which includes only the Work Statement and the Evaluation Criteria to be used for selection of the awardee. After examining this, a full text version of the RFP must be requested in writing for those offerors interested in responding. FAX requests are acceptable for the full text version only. All proposals from responsible sources will be considered by NIAID. This advertisement does not commit the Government to make an award. No collect calls will be accepted.

Requests for the RFP are to be directed in writing to:

Phil Hastings
Contracts Management Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0194
FAX: (301) 402-0972

SERVICES RESEARCH COMPETITIVE SUPPLEMENTS TO CLINICAL THERAPEUTIC RESEARCH GRANTS

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: MH-94-008

P.T.

National Institute of Mental Health

Letter of Intent Receipt Date: May 8, 1994

Application Receipt Date: June 8, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Competitive supplements to expand ongoing funded clinical therapeutic research grants into the area of service research will be available. Supplemental grant support is designed to help move mental health treatments more rapidly from the testing of efficacy (i.e., whether the treatment works under controlled conditions in a population with a well-defined mental disorder) into testing of effectiveness (i.e., whether the same treatment works in everyday practice and across settings).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Services Research Competitive Supplements to Clinical Therapeutic Research Grants, is related to the priority area of mental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications will only be considered for currently funded grants with at least one year remaining, ending no later than March 30, 1996. Such funding could be supplementary to a competitive renewal grant. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) competitive supplement (S01) mechanism and can supplement the following types of grants: R01, R10, R37, P01, P20, P30, P50.

FUNDS AVAILABLE

It is anticipated that at least \$1,000,000 in direct costs will be made available so that a minimum of seven awards can be made. Each award will have a maximum yearly direct cost amount of \$150,000, but not to exceed 40 percent of the annual direct cost of the parent grant.

RESEARCH OBJECTIVES

Following are examples of the types of clinical services research issues that would benefit from expansion of ongoing clinical therapeutic research grants.

- o Studies testing the effectiveness of proven mental health treatments when employed in everyday practice and settings (e.g., primary care settings, nursing homes, community mental health centers, outpatient clinics).
- o Studies testing proven treatments with new populations, such as racial or ethnic minorities, patients with co-occurring mental, substance abuse, or medical conditions.
- o Studies testing the effectiveness of proven mental health treatments when administered by providers who more fully represent the range and expertise of providers expected to deliver the treatment in everyday practice and settings.
- o Studies of the delivery of treatment, such as how to provide coordinated treatment and rehabilitation services and select modalities which best match the patient's/client's needs.
- o Studies that measure an expanded range of outcomes (beyond symptom reduction), such as functional capacity, quality of life, or cost in relation to outcome.
- o Research on improving accessibility of efficacious treatments for patients/clients in need of such treatments.
- o Financing and cost issues relating to therapeutic interventions, e.g., cost-effectiveness, cost-benefit, and cost-utility research.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 8, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIMH staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Robert Prien at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are to use the grant applications form PHS 398 (rev. 9/91). Application kits containing the necessary forms and instructions for regular research grants may be obtained from the offices of sponsored research at most universities, colleges, medical schools, and other major research facilities; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the program office listed under INQUIRIES.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title (Services Research Competitive Supplements to Clinical Therapeutic Research Grants) and number (MH-94-008) must be typed on line 2a of the face page of the application form and the YES box must be marked.

The signed original and five legible copies of the completed application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

AWARD CRITERIA

Applications received in response to this announcement will compete with others submitted to NIMH for funding. In granting awards, the following criteria are considered: program relevance, quality of application as documented by IRG and Council recommendation, and program balance.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Robert F. Prien, Ph.D.
Division of Clinical and Treatment Research
National Institute of Mental Health
5600 Fishers Lane, Room 18-105
Rockville, MD 20857
Telephone: (301) 443-4527
FAX: (301) 443-6000

Direct inquiries regarding grants management issues to:

Diana Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065
FAX: (301) 443-6885

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants and Federal Regulations 42 CFR, Part 52 "Grants for Research Projects" and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372.

CLONING AND SEQUENCING THE BRCA1 GENE

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: CA-94-021

P.T.

National Cancer Institute

Application Receipt Date: June 14, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Biology, Diagnosis and Centers, National Cancer Institute (NCI) invites the submission of research project grant applications for support to clone and sequence the BRCA1 gene. The aim of this RFA is to foster and stimulate collaborations among investigators who can expedite the process of cloning and sequencing the BRCA1 gene. It is expected that the achievement of this goal will lead to new research opportunities for prevention, screening, early detection, and treatment of breast and ovarian cancer, and perhaps other malignancies.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cloning and Sequencing the BRCA1 Gene, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications can be from single or multiple institutions (collaborating institutions, consortia). Foreign institutions may also participate in Laboratory or Clinical Programs through subcontract or consortium arrangements. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01) as its funding mechanism. Applicants will be responsible for the planning, direction, and execution of the proposed projects. The total proposed project period for each application submitted in response to this RFA must not exceed two years. Recognizing the complexity of this initiative, it is appropriate to include several specific aims within a single research project application. The total proposed direct costs for the first year may not exceed \$1,400,000. This does not include indirect costs on a subcontract that appears as a direct cost by the applicant organization. The anticipated award date is August 15, 1994.

The award and level of support depends on receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose.

This RFA is a one-time solicitation. At this time, the NCI has not determined whether or how this solicitation will be continued beyond the present RFA period.

FUNDS AVAILABLE

Approximately \$2,000,000 in total costs per year will be committed specifically to fund applications submitted in response to this RFA. It is anticipated that at least one award will be made.

RESEARCH OBJECTIVES

Several families with high frequencies of early-onset breast cancer and ovarian cancer have been linked to a genetic marker, BRCA1, at chromosome 17q21. Mutational change at the BRCA1 locus may be a critical step in the pathway ultimately leading to breast cancer in at least some patients because there is an increased incidence of breast cancer in individuals who inherit mutations at that locus. The same reasoning applies to ovarian cancer.

The epidemiologic pattern is compatible with the transmission of a dominant allele of a gene that predisposes women to breast and ovarian cancer. Characterization of DNA from familial breast cancers indicates that allelic loss occurs at the locus called BRCA1 on chromosome 17q21, consistent with the interpretation that this locus contains the functional equivalent of a tumor suppressor gene, the loss of which may lead to the development and maintenance of a neoplastic state. One of several ways to find and isolate the BRCA1 gene would be to determine the complete sequence of the 400-500 kilobase genomic region thought to contain BRCA1 using DNA from persons thought to inherit wild-type or mutant genes, and DNA from breast tumors. Isolation or identification of a gene or genes at chromosome 17q21 could, therefore, be an outcome of profound importance to understanding the etiology of certain cancers in women.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this RFA. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NCI program staff listed under INQUIRIES.

The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA number and title must be typed on line 2a of the face page of the application form and the YES box must be marked.

Applications must be received by June 14, 1994.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Referral Officer
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636
6130 Executive Boulevard
Rockville, MD 20852

It is important to send these copies at the same time that the original and three copies are sent to DRG; otherwise, the NCI cannot guarantee that the application will be reviewed in competition for this RFA.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the DRG for completeness and for responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Applications will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review will be provided by the National Cancer Advisory Board.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA and inquiries about whether or not specific proposed research would be responsive are strongly encouraged.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Cheryl Marks
Division of Cancer Biology, Diagnosis and Centers
National Cancer Institute
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-7028
FAX: (301) 402-1037

Direct inquiries regarding fiscal matters to:

Ms. Sara Stone
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800 Ext. 266
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.396, Cancer Biology Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, 42 U.S.C. 241, as amended; Public Law 100-607, 42 USC 285 and 285a) and administered under HHS grants policies. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

IN VIVO ACTIVITIES OF LACTOFERRIN

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: HD-94-019

P.T.

National Institute of Child Health and Human Development

Application Receipt Date: July 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Endocrinology, Nutrition and Growth (ENG) Branch of the Center for Research for Mothers and Children, National Institute of Child Health and Human Development (NICHD) announces the availability of an RFA for support of investigations of in vivo activities of lactoferrin in human beings and animals.

Lactoferrin is a 78,000-dalton metal-binding single-chain glycoprotein found in milk and other exocrine secretions. It is the major protein component of human colostrum whey, with concentrations as high as 6 mg/ml. Since the human lactoferrin gene has been cloned, overexpression and large scale lactoferrin production are now possible.

It is important to derive hypotheses about biological function from the extensive structural knowledge about the lactoferrin molecule and test them in vivo. This is needed in order to plan testing of the utility and advisability of feeding lactoferrin-containing formula to infants. The impending addition of lactoferrin to all infant formula may make future definitive trials seem unethical or impractical.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, In Vivo Activities of Lactoferrin, is related to the priority area of childhood nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Applications in response to this RFA will be funded through the research project grant (R01) and FIRST Award (R29) program of the NIH. This RFA is for a single competition. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed by a Division of Research Grants (DRG) study section. However, if it is determined that there is a sufficient continuing program need, the NICHD may announce a request for competitive continuation applications. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest anticipated award date is April 1, 1995.

FUNDS AVAILABLE

It is anticipated that three or more grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds. To fund these awards, the NICHD has set aside \$750,000 for direct costs in the first year.

RESEARCH OBJECTIVES

Background

Three striking *in vitro* properties of lactoferrin may be of importance to its biological function: its ability to bind and release a wide variety of metal ions, especially ferric iron (Fe), its ability to bind cations, and its binding to a number of different types of cells. In iron-free form it has pronounced bacteriostatic properties *in vitro*, probably dependent on its ability to bind adventitious iron extremely tightly, so depriving bacteria of iron essential for growth. The bacteriostatic properties of human milk are thought to derive largely from the high concentrations of lactoferrin present. In addition, sequestration of iron by lactoferrin inhibits iron-catalyzed free radical damage to cells. For these reasons, and because of its widespread occurrence in an frequent association with species such as lysozyme and immunoglobulins, lactoferrin is regarded as a component of the body's defense mechanisms. Lactoferrin is also a component of neutrophil secretory granules.

Lactoferrin has the capacity to bind reversibly two Fe ions concomitantly with two CO₃⁼ or other anions. The two lactoferrin structural cavities in which Fe and the anion are bound seem much larger than necessary for this function. To some this has suggested that lactoferrin may function to bind anionic toxins and xenobiotics. All the Mn in human milk is bound to lactoferrin, and lactoferrin has been suggested to have a role in Zn binding and heavy metal absorption. The physiological importance of transferrin in A1 binding may also apply to lactoferrin.

The ability of lactoferrin to bind to a variety of normal and leukemic blood cells suggests that the lactoferrin released by neutrophilic leukocytes may play a role in modulating the immune and inflammatory responses. Lactoferrin promotes the aggregation of neutrophils and their adhesion to epithelial cells, and may be the agent that causes neutrophils to accumulate at inflammatory sites. Iron-saturated lactoferrin is a highly active inhibitor of myelopoiesis.

Other observations that focus on the ability of lactoferrin to interact with cells include its activity as an essential growth factor for lymphocyte cell lines, its partial sequence homology with a group of lymphoma transforming proteins, its interference in the receptor-mediated uptake of chylomicron remnants into the liver, and the observation that some antibacterial activities of lactoferrin depend on actual contact with bacteria rather than simple sequestration of iron.

Scope

This RFA solicits applications for *in vivo* studies of effects of lactoferrin in human beings or animals. The goal is to learn the significance of human milk lactoferrin to human infants or nursing women, but it is understood that some kinds of direct experiments in humans are not advisable without promising preclinical studies. Animal model studies are, therefore, also of interest provided they involve species-specific lactoferrin or the use of heterologous lactoferrin that can be shown to mimic homologous lactoferrin in adherence to receptors or effects on cells *in vitro*. A focus on effects of lactoferrin that apply to milk rather than other external secretions is preferred.

The scope of this RFA, therefore, includes animal and human studies of the biological effects of lactoferrin. It does not include *in vitro* bacterial or tissue culture investigations. It is recognized that some preliminary experiments *in vitro* may be required for certain *in vivo* projects. Nevertheless, the priority for funding each application will be determined by reviewers on the basis of the relative merit of the *in vivo* studies proposed, and the likelihood that the research will proceed to the whole animal or human level within the terms of the recommended award. Funded applications that fail to demonstrate progress towards this stage may be phased out before the recommended term of the award is completed.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91). These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248. Applications must be received by July 19, 1994. Potential applicants must request the detailed information included in the RFA before preparing an application.

REVIEW CONSIDERATIONS

Applications will be reviewed by NICHD staff for responsiveness to the RFA. Applications judged to be nonresponsive will be returned. The applicant may resubmit the application and have it assigned for review in the same manner as unsolicited grant applications.

Responsive applications may be subjected to a triage by a peer-review group to determine their scientific merit relative to the other applications received in response to this RFA. The NIH will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official. Those applications judged to be competitive will be further evaluated for scientific/technical merit by a review group convened solely for this purpose by the Division of Scientific Review, NICHD. Criteria for the initial review are described in the RFA. Following review by the Initial Review Group, applications will be evaluated by the National Advisory Child Health and Human Development Council for program relevance and policy issues before awards for meritorious proposals are made.

AWARD CRITERIA

The anticipated award date is April 1, 1995. Scientific merit and technical proficiency, based on the demonstrated and projected capabilities described in the application will be the predominant criteria for determining funding priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Ephraim Y. Levin, M.D.
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Building, Room 4811
Bethesda, MD 20892
Telephone: (301) 496-5593

Direct inquiries regarding fiscal matters to:

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
6100 Building, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-1303

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SMALL GRANTS FOR NEW ALCOHOLISM TREATMENT RESEARCHERS

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: AA-94-007

P.T.

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Date: August 11, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is seeking Small Grants applications to stimulate and facilitate the entry of promising new investigators into the field of alcoholism treatment research. This pilot program is designed to provide rapid review and funding decisions for applications. The NIAAA encourages investigators at the beginning of their research careers to submit applications for small-scale research projects (up to \$10,000 for direct

costs for one year) related to issues surrounding assessment and treatment of alcoholism.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Small Grants for New Alcoholism Treatment Researchers, is related to the priority areas of alcohol abuse reduction and alcoholism treatment. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applications may be submitted by public and private non-profit and for-profit organizations such as universities, colleges, hospitals, treatment facilities, research institutions, units of State or local government, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply.

To be eligible for this award, the proposed Principal Investigator must be at the beginning of her/his research career and be able to secure a meaningful mentoring relationship with a more experienced researcher. Such experience must be in some way relevant to the project, though it need not be specifically in the field of alcoholism treatment. Special target groups for this award include pre-doctoral graduate students, post-doctoral fellows, as well as clinicians now working in the field of alcoholism treatment. Investigators who have received a research project grant (R01), small grant (R03), exploratory/development grant (R21), First Independent Research Support and Transition (FIRST) award (R29), scientist development award for clinicians (K20), or a scientist development award (K21) are not eligible to apply.

MECHANISMS OF SUPPORT

These awards will use the small grant (R03) mechanism. Support may be requested for up to one year for up to \$10,000 for direct costs. These awards are not renewable, but a one-year no cost extension may be requested. The award may not be used for salary support of either the Principal Investigator or mentor, but may be used to support the costs of technicians and for dissertation research.

FUNDS AVAILABLE

It is estimated that approximately \$100,000 will be available for approximately seven to eight grants under this RFA, in FY 1995. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Additional applications may also be funded if their scientific and technical merit warrants it. Although this program is provided for in the financial plans of NIAAA, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

With competition for NIAAA grant funds increasing, academic careers becoming more dependent on funded grants, and costs associated with preparation of grant applications escalating, investigators face numerous challenges in entering a new research arena. The objective of this RFA is to stimulate and encourage promising new researchers to enter the field of alcoholism treatment research. It is anticipated that the prospects for funding meritorious projects under this RFA will likely be more favorable than is the case with larger award requests.

The Treatment Research Branch of the Division of Clinical and Prevention Research supports research on management of alcoholism, alcohol abuse, and alcohol-related disorders, including evaluation of new treatment methods, assessment of effectiveness of various kinds of behavioral and pharmacologic interventions, development of new diagnostic instruments, and elaboration and refinement of assessment/methodologies for research on effectiveness and costs of treatment. The Branch also supports health services research on the organization, financing, delivery, and effectiveness of alcoholism treatment. This award is designed as a rapid mechanism that provides "seed" funds for investigators who have not received research or career development grant funds from NIAAA in the past. It supports primarily:

- o Pilot projects on treatment issues and outcomes;
- o Psychometric analyses and instrument development; and
- o Secondary analyses of existing data sets.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301-594-7248; and from the NIAAA program administrator listed under INQUIRIES.

Applications must be received by August 11, 1994. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NIAAA. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NIAAA staff will contact the applicant to determine whether to return the application to the applicant or request the applicant to revise and resubmit it as a regular small grant application for review in competition with unsolicited applications at the next review cycle.

Applications may be triaged by an NIAAA peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant and institutional official. Those applications judged to be competitive will undergo further scientific merit review in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIAAA. Applications may also be reviewed by mail ballot.

Review Criteria

Criteria to be used in the scientific and technical merit review of Small Grants for New Alcoholism Treatment Researchers applications will include the following:

1. The scientific, technical, health, or medical significance and originality of the proposed research.
2. The appropriateness and adequacy of the research design and methodology proposed to carry out the proposed research.
3. Ability to secure a mentoring relationship with an experienced researcher.
4. The adequacy of the qualifications and relevant research experience of the principal investigator and the principal investigator's mentor.
5. The availability of adequate data, facilities, general environment for the conduct of the proposed research, other resources, and collaborative arrangements necessary for the research.
6. The reasonableness of budget estimates for the proposed research.
7. Where applicable, the adequacy of procedures to protect or minimize effects on human subjects and the environment.
8. Conformance of the application to the NIH policy on inclusion of women and minorities in study populations.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Joanne Fertig, Ph.D.
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 505
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-0635
FAX: (301) 443-8774
Email: JFertig@WILLCO.NIAAA.NIH.GOV

Direct inquiries regarding fiscal matters to:

Joseph Weeda
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 504
6000 Executive Boulevard
Rockville, MD 20892-7003
Telephone: (301) 443-4703
FAX: (301) 443-3891

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authorization of the Public Health Service Act, Sections 301 and 464H, and administered under the PHS policies and Federal Regulations at Title 42 CFR Part 52, "Grants for Research Projects;" Title 45 CFR Parts 74 and 92, "Administration of Grants;" and 45 CFR Part 46, "Protections of Human Subjects." This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: DE-94-004

P.T.

National Institute of Dental Research

Letter of Intent Receipt Date: August 10, 1994

Application Receipt Date: September 12, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Dental Research (NIDR) invites new and competing applications proposing National Research Service Award (NRSA) Institutional Research Training Grant (T32) programs in basic biomedical, behavioral and clinical sciences pertaining to oral health research. The primary objective is to develop highly qualified, clinical investigators by supporting postdoctoral training of individuals with a D.D.S., D.M.D., or equivalent degree, who are committed to a career in oral health research. The secondary objective is training of pre- and post-Ph.D. biomedical and behavioral scientists in oral health research.

Programs must be relevant to the goals of the NIDR. There is a need to increase the number of clinical investigators in order to take advantage of opportunities for transfer of fundamental knowledge to improve oral health care of the public. To address this need, applications must allocate not less than two postdoctoral positions to trainees with a declared interest in training to conduct patient-oriented or patient-related research. The remaining positions may be allocated to basic or clinical research training, in the array of biomedical and behavioral research areas pertaining to the NIDR's mission.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, NRSA - Institutional Training Applications, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, public, and private institutions such as dental schools and dental research institutions. Only one application may be submitted by an institution unless the training programs are in distinctly different areas of oral health research.

Training is to be provided at one or more of the following levels: (1) dentists pursuing postdoctoral clinical research training; (2) dentists pursuing a Ph.D. or equivalent degree in basic biomedical or behavioral science; (3) baccalaureate degree holders pursuing a Ph.D. or equivalent degree; (4) Ph.D. degree holders pursuing postdoctoral research training although, generally, they are expected to apply for an individual postdoctoral NRSA fellowship (F32).

Postdoctoral trainees who have received, as of the beginning of an appointment, a D.D.S., D.M.D., or equivalent dental degree from an accredited domestic or foreign institution must be given preference. Predoctoral trainees must have received a baccalaureate degree as of the beginning of the appointment and be enrolled in a graduate program leading to the award of a Ph.D. or an equivalent degree in biomedical or behavioral oral health research. Trainees must be citizens or noncitizen nationals of the United States, or have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551).

MECHANISM OF SUPPORT

Awards resulting from this RFA will be the National Institutes of Health (NIH), NRSA Institutional Research Training Grants (T32). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period may not exceed five years. Trainees may receive up to five years of NRSA support at the predoctoral level and three years of support at the postdoctoral level. The anticipated award date is July 1, 1995.

FUNDS AVAILABLE

In response to this RFA, the NIDR expects to make up to three new or competing awards, each with six postdoctoral positions over the five-year period, with two appointments in each of the first, second and third years. Three predoctoral positions may be requested over the five year period. The estimated total funding for the first year of support is \$240,000.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 10, 1994, a letter of intent that includes a descriptive title of the proposed research training program, the name, address, and telephone number of the program director, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDR staff to estimate the potential review workload and to avoid conflicts of interest in the review.

The letter of intent is to be sent to Dr. Thomas Valega at the address listed under INQUIRIES.

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact Dr. Valega early in the planning phase of application preparation. This will help ensure that applications are responsive to the RFA.

Applications are to be submitted on form PHS 398 (rev. 9/91). Application forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the program staff listed under INQUIRIES.

REVIEW CONSIDERATIONS

Applications may be subjected to triage by the NIDR Special Grants Review Committee, a standing NIH initial review group, to determine their merit, relative to others received in response to the RFA. Applications judged to be competitive will be evaluated for scientific and technical merit by the review committee.

The following factors will be considered in the review: The training program objectives, design and direction; the training environment; the program director; mentors; training record; recruitment and retention of appointees; and instruction on scientific integrity.

Secondary review will be by the National Advisory Dental Research Council. The NIDR will notify the applicant of the Council's action shortly after its meeting.

AWARD CRITERIA

The earliest award date is July 1, 1995. Funding decisions will be based on the Special Grant Review Committee's and Council's recommendations; the need for research personnel in particular program areas, including the need to train clinical investigators; and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Thomas M. Valega, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 594-7617
FAX: (301) 594-7616

Direct inquiries regarding fiscal matters to:

Theresa Ringler
Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

NRSA Institutional Research Training Grants are made under the authority of Section 487 of the Public Health Service (PHS) Act as amended (42 USC 288). Title 42 of the Code of Federal Regulations, Part 66, is applicable to this program. This program is also described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SPECIALIZED CENTERS OF RESEARCH IN HEMATOPOIETIC STEM CELL BIOLOGY

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: HL-94-010

P.T.

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: May 31, 1994

Application Receipt Date: September 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The objectives of this program are to advance our knowledge of basic stem cell biology in areas of stem cell isolation, quantitation by in vivo assay, in vitro and in vivo growth and replication, gene insertion, and engraftment. This basic knowledge will be applied clinically to enhance our ability to achieve successful hematopoietic stem cell therapy to cure both genetic and acquired diseases and to perform successful gene therapy using the hematopoietic stem cell as the target for gene transfection and for life-long expression of normal genes.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Specialized Centers of Research (SCOR) in Hematopoietic Stem Cell Biology, is related to the priority areas of maternal and infant health, and cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-01) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by for-profit and non-profit domestic institutions, public and private, such as universities, colleges, hospitals, and laboratories. This RFA is intended to support SCOR grants for basic and clinical investigations. Therefore, applications that include only basic or only clinical research will not be responsive to this RFA. In addition, clinical research projects focused on large epidemiologic studies or large clinical trials will be considered unresponsive to this RFA. Awards will not be made to foreign institutions; however, under exceptional circumstances, a foreign component critical to a project may be included as a part of that project. Women and minority investigators are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the National Heart, Lung, and Blood Institute (NHLBI) SCOR (P50) grant to support this research program. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

Basic and Clinical Research

The overall concept of a SCOR program focuses on scientific issues related to the mission of the NHLBI. It is essential, therefore, that all applications include both basic and clinical research. Interactions between basic and clinical scientists are expected to strengthen the research, enhance transfer of fundamental research findings to the clinical setting, and identify new research directions. Plans for transfer of findings from basic to clinical studies should be described.

FUNDS AVAILABLE

Applicants may request up to \$1,125,000 in direct costs, not including indirect costs for collaborating institutions, in the first year with a maximum increase of no more than four percent in each additional year requested in the application. Award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that at least two SCOR grants will be funded. NHLBI's FY 1996 plans for this initiative include a maximum of \$4.4 million. The specific amount to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds.

RESEARCH OBJECTIVES

Background

The production of blood cells, or hematopoiesis, takes place in the bone marrow. Hematopoiesis begins with the most primitive, pluripotent hematopoietic stem cell, which has a frequency of less than one per 10,000 nucleated bone marrow cells. The stem cell can either replicate and remain a stem cell or differentiate into myeloid or lymphoid stem cells, which in turn can further proliferate and mature, ultimately giving rise to all the circulating blood cells. Each of these complex hematopoietic pathways is under the influence of one or more hematopoietic growth factors or other cytokines that enhance cellular proliferation and maturation, as well as inhibitory activities which prevent proliferation. These activities are generated and act within the marrow microenvironment.

Currently, allogeneic bone marrow transplants are recognized as a treatment of choice for chronic myelogenous leukemia, acute leukemias failing initial treatment, aplastic anemia, and several lethal disorders of the immune system and of hematopoiesis. Allogeneic bone marrow transplantation has become increasingly used as a cure for a variety of genetic defects of the hematopoietic and immune systems, and for lipid storage diseases. Genetic diseases that have been successfully cured by bone marrow transplantation include Cooley's anemia, sickle cell anemia, severe combined immunodeficiency, Wiskott-Aldrich syndrome, Fanconi anemia, Blackfan-Diamond anemia, ataxia telangiectasia, infantile agranulocytosis, Chediak-Higashi disease, chronic mucocutaneous candidiasis, mucopolysaccharidosis, cartilage-hair hypoplasia, Gaucher's and other lipid storage diseases. Some of these diseases, such as Cooley's anemia (beta-thalassemia) and sickle cell anemia, are major worldwide public health problems. Others are devastating orphan diseases that are extremely costly to treat. Collectively, these genetic diseases occur in tens-of-thousands of births per year.

It is also recognized that several malignant disorders are sensitive to agents that have, as their dose-limiting toxicity, myelo-ablation. This knowledge, along with the initial success of marrow and peripheral blood-derived autografts administered after myelo-ablative therapy, have clearly defined the rationale for the use of hematopoietic stem and progenitor cells in the treatment of several non-hematopoietic malignancies, including breast cancer, which occurs with alarming frequency.

At present, over 5,000 HLA-matched marrow allografts are performed annually. Only about 35 percent of transplant candidates have a suitably matched sibling marrow donor. However, the development of a national registry of volunteer marrow donors (National Marrow Donor Program) and improvements in histocompatibility testing have provided the alternative of marrow transplants from unrelated donors. About 40 percent of patients who activate or formalize their searches for an unrelated donor are now able to be transplanted. Hence, about 60 percent of patients with transplantable disorders are able to get a transplant. The significant cost of the procedure, which could be as much as \$200,000 not including the possible long-term care for chronic graft-versus-host disease, may preclude many from benefiting from this form of treatment.

Proposed Research

The proposed research should advance our knowledge of basic stem cell biology. This new knowledge should then be applied clinically to enhance our ability to (1) achieve successful hematopoietic stem cell therapy to cure both genetic and acquired diseases and/or (2) perform successful gene therapy using the hematopoietic stem cell as the target for gene transfection and for life-long expression of normal genes. The primary focus of the overall SCOR grant application should be on non-malignant hematologic diseases.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research; the name, address, and telephone number of the principal investigator; the identities of other key personnel and participating institutions; and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 557A
Bethesda, MD 20892

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248.

Applications must be received by September 15, 1994.

REVIEW CONSIDERATIONS

Applications will be judged on the basis of the scientific and technical merit of the proposed research; the qualifications and research experience of the investigators; the collaborative interaction among basic and clinical research components; the adequacy of the environment; and the appropriateness of the budget.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Alan S. Levine, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung and Blood Institute
Federal Building, Room 5A12
Bethesda, MD 20892
Telephone: (301) 496-5911
FAX: (301) 496-9940

Direct inquiries regarding fiscal and administrative matters to:

Ms. Jane Davis
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 594-7436
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.839, Blood Diseases and Resources. Awards will be made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or Health Systems Agency review. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded under this RFA.

INVESTIGATOR GRANTS FOR CLINICAL CANCER THERAPY RESEARCH

NIH GUIDE, Volume 23, Number 14, April 8, 1994

RFA AVAILABLE: CA-94-014

P.T.

National Cancer Institute

Letter of Intent Receipt Date: August 5, 1994
Application Receipt Date: September 21, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Cancer Therapy Evaluation Program (CTEP) and the Biological Response Modifiers Program (BRMP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) invites research grant applications (R01) for the conduct of therapeutic clinical trials research employing new agents, concepts, or strategies for the treatment of cancer. This initiative is aimed at drawing new clinical investigators into this area of research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Investigator Grants for Clinical Cancer Therapy Research, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

An important principle to remember is that the more extensive the prior independent research experiences, regardless of funding sources, the greater likelihood there will be diminished priority for award.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) as its funding mechanism. The total project period for applications submitted in response to the present RFA may not exceed four years. The total

direct cost for the four year period may not exceed \$500,000. The direct cost in any budget period should not exceed \$150,000. The anticipated award date is July 1995.

This RFA is a one-time solicitation for new applications for award in FY 95. However, the NCI has plans to re-issue this RFA for funding in 1996 and 1997. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$1,500,000 in total costs per year for four years will be committed to fund specifically applications submitted in response to this RFA. It is anticipated that eight new individual awards will be made. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose.

RESEARCH OBJECTIVES

The goal of this initiative is to provide a suitable mechanism for the training and funding of clinically oriented physician investigators, especially those involved in translating basic research into new cancer treatments. Qualified clinical investigators are encouraged to develop R01 grant applications for the conduct of cancer clinical trials research on new therapeutic agents and modalities. Grant applications must include clinical trials involving human subjects and designed to ultimately improve cancer survival. The clinical trials must have a strong rationale and be based upon preclinical data generated by the applicant or others that support the underlying hypotheses. New clinical therapeutic trials employing drugs (including differentiating agents), biologics (including cytokines, antibodies), vaccine strategies, radiation, or surgery whether used as a single agent/modality or in combination are appropriate. Investigators are urged especially to address the more difficult therapeutic challenges, including the most common malignancies (e.g., breast, ovarian, prostate).

Laboratory studies to monitor patients or to study the mechanism of antitumor effect and resistance should be included. The laboratory studies should be in support of the clinical trial, such that their conduct leads to a greater understanding of the relationship of the therapy and biological changes in the patient or the mechanism of action of an anti-tumor response. Laboratory studies would include pharmacokinetic studies of cytotoxic, immune-modulating, differentiation-inducing, and/or targeted therapeutic agents or relevant pharmacodynamic correlative studies. Measurement of particular biological responses would also be desirable particularly when this information would be relevant to the interpretation of the success or failure of the therapy in individual patients on the clinical trial.

It is expected that a significant level of effort, at least 25 percent, will be committed to the research project by the Principle Investigator.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research". See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 5, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. This letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. It is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent is sent to:

Ms. Diane Bronzert
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

APPLICATION PROCEDURES

Applications must be received by September 21, 1994. If an application is received after that date, it will be returned. The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this RFA. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NCI program staff listed under INQUIRIES.

The application must include the following documentation to be considered for review:

- o A draft of the clinical protocol must be included in the Appendix. Documentation of the status of Human Subjects and IRB approval should be included.
- o Documentation for the composition of the proposed study population in terms of gender and racial/ethnic group together with a rationale for its choice must be included in the Human Subjects section.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness and for responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle. Questions concerning the responsiveness of proposed research to the RFA are to be directed to program staff listed under INQUIRIES.

AWARD CRITERIA

Applications considered by the National Cancer Advisory Board will be considered for award based upon (a) scientific and technical merit; (b) availability of funds; and (c) programmatic priorities. Preference will also be given to clinical investigators who are new to this research area. The anticipated date of award is July 1995.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic to:

Dr. Toby Hecht
Division of Cancer Treatment
National Cancer Institute
FCRF 1052, Room 253
Bethesda, MD 20892
Telephone: (301) 846-1098
FAX: (301) 846-5429

Direct inquiries regarding fiscal matters to:

Ms. Eileen M. Natoli
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 256
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended, Public Law 99-158, 42 USC 241 and 285) and administered under HHS grants policies. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

MINORITY DISSERTATION RESEARCH GRANTS IN MENTAL HEALTH

NIH GUIDE, Volume 23, Number 14, April 8, 1994

PAR AVAILABLE: PAR-94-

P.T.

National Institute of Mental Health

Application Receipt Dates: April 11, August 10, December 13

THIS IS A NOTICE OF AVAILABILITY OF A PROGRAM ANNOUNCEMENT (PA); IT IS ONLY AN ABSTRACT OF THE PA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE PROGRAM ANNOUNCEMENT, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE PA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The purpose of this program announcement (PA) is to stimulate and encourage minority doctoral candidates to pursue research careers in any area relevant to mental health and/or mental disorders.

The intent of the dissertation research grants is to attract larger numbers of minority students as mental health investigators and to assist in providing a positive and constructive research experience that will stimulate them to pursue research careers in this field.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Minority Dissertation Research Grants in Mental Health, is related to the priority area of mental health and mental disorders. Potential applicants

may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY

The applicant investigator applying for a dissertation research grant must be enrolled in an accredited doctoral degree program in the behavioral, biomedical, or social sciences and must have approval of the dissertation proposal by a named committee. A student applying for a Minority Dissertation Research Grant in Mental Health must be an individual from a minority group who is conducting or intends to conduct dissertation research on any problem related to mental health or mental disorder. Research topics must fit within one or more of the areas described in the Attachment to the PA, which is available from program staff listed under INQUIRIES. Minority groups qualifying for support under this program announcement include Black Americans, Hispanic Americans, American Indians, Alaskan Natives, and Asian and Pacific Islanders.

The applicant must be a registered doctoral candidate in resident or nonresident status. All requirements for the doctoral degree other than the dissertation (and for students requiring it, the clinical internship) must be completed by the time of the award. This information and the approval of the dissertation topic by a named committee must be verified in a letter of certification from the thesis chairperson and submitted with the grant application (see Application Procedures).

The applicant institution administering the grant on behalf of the proposed applicant must be domestic. Applications may be submitted by any public or private non-profit university, college, or professional school. The doctoral candidate must be a citizen or noncitizen national of the United States or hold a permanent residence visa. Academic institutions are encouraged to facilitate application from qualified doctoral candidates.

MECHANISM OF SUPPORT

The mechanism of support is the National Institutes of Health (NIH) small grant (R03). Grants to support dissertation research will provide no more than \$25,000 in direct costs. Awards will depend on the availability of funds.

RESEARCH OBJECTIVES

Research objectives of the Minority Research Dissertation Grants in Mental Health include, but are not limited to, studies in the basic, clinical, and services research areas pertinent to mental health and mental disorders. In the basic neurosciences and behavioral sciences, studies are supported in molecular and cellular neuroscience, neurobiology, and in the biological aspects of behavior; in psychopharmacology and neuropharmacology; in cognitive and language processes; in the regulation and maintenance of behavior; in personality, emotion, and psychosocial and family processes and factors influencing neural, behavioral, psychological and sociocultural development. Studies of the biological, psychological, and psychosocial aspects of stress, including post-traumatic stress, are supported, as is research in behavioral medicine, psycho- and neuroimmunology, neurovirology, and Acquired Immunodeficiency Syndrome (AIDS).

Studies of the epidemiology, etiology, diagnosis, treatment, and prevention of distinct mental disorders are supported. Specific clinical research programs emphasize studies in the psychopathology, mental, and behavioral disorders of children, adolescents, and the aging, as well as others devoted to schizophrenia, mood, anxiety, and personality disorders.

In services research, studies are supported on service delivery within the mental health system and on the provision of mental health services in other types of health care settings. Studies are supported also on economic factors influencing supply, demand and costs of mental health services. In addition, the NIMH supports research on mental health factors related to antisocial, violent, and abusive behavior, and studies of law and mental health interactions.

Scope of Awards

Dissertation Research Grants usually are awarded for a period of 12 months but may be extended without additional funds for up to 24 months.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the PA for details.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), which is available from university offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application.

Applications will be accepted for the receipt dates of April 11, August 10, or December 13.

Special Instructions

Special instructions included in the complete Program Announcement must be followed.

The applicant must submit the original and five copies of the completed application, which includes a detailed narrative project description (not to exceed 10 pages) and letter of certification (also an original and five copies) to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

These application will be reviewed initially by non-Federal experts in the review groups of the NIMH, and a second level of review will be conducted by senior NIMH staff members. Reviewers will take into account the applicant's stage of development and the importance of the dissertation project as a learning experience that is part of the applicant's graduate education. Detailed review criteria are in the complete PA. General criteria in the review of these applications include:

- o The potential significance of the problem to be investigated
- o The relationship of the proposed research to expanding the knowledge base in area(s) related to mental health and/or mental disorders
- o The scientific quality of the proposal, including appropriateness of the research design and methodology
- o Personal qualifications of the candidate and promise as a research investigator in areas relevant to the proposal
- o Suitability and availability of faculty advice, support, and supervision and of facilities necessary to carry out the research.

It is the intent to provide review results and announce funding decisions within 4 months after the submission date.

AWARD CRITERIA

Final funding decisions are based on recommendations of the reviewers; relevance of the project to NIMH program support areas; program balance; and availability of appropriated funds.

INQUIRIES

Written and telephone requests for the PA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Requests for the PA and attachments, and inquiries regarding programmatic issues may be directed to:

Stanley F. Schneider, Ph.D.
Division of Neuroscience and Behavioral Science
National Institute of Mental Health
5600 Fishers Lane, Room 11-103
Rockville, MD 20857
Telephone: (301) 443-4347
FAX: (301) 443-4822

Inquiries related to fiscal matters or grants management issues may be directed to:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Awards are made under the authorization of the Public Health Service Act, Title IV, Part A, Public Law 78-410, as amended, and administered under PHS grants policies and regulations 42 CFR 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

STRATEGIES TO REDUCE HIV SEXUAL RISK PRACTICES OF DRUG USERS

NIH GUIDE, Volume 23, Number 14, April 8, 1994

PA NUMBER: PA-94-

P.T.

National Institute on Drug Abuse

PURPOSE

The purpose of this Program Announcement is to introduce a major research effort to develop and evaluate the efficacy of multi-phase behavioral change interventions designed to reduce high-risk sexual practices among injection drug users (IDUs) and/or crack smokers. It is expected that by implementing strategies in different community settings that are commonly utilized by drug users (e.g., primarily neighborhood settings, but also drug treatment facilities, sexually transmitted disease (STD) clinics, storefronts, etc.) there can be a substantial decrease in the probability of HIV exposure by reducing drug-related sexual risk behaviors. As the AIDS epidemic enters the midyears of the second decade, 339,000 cases of AIDS have been reported to the Centers for Disease Control (CDC) as of September 30, 1993. Of the women infected with the virus via heterosexual intercourse, 60 percent reported their sexual partners to be men who injected drugs. Some of these male injectors were also at risk from sexual contact with other men -- creating a bisexual "bridge" population to women's infection. Additionally, with many women being infected through their own or their sexual partners' drug use, heterosexual transmission of the virus from women to men is now occurring more frequently than originally believed possible. The goal of this research is to gain knowledge about the social and behavioral factors related to sexual risk taking and to develop, implement, and evaluate strategies that reduce sexually and drug related risk behaviors.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Strategies to Reduce HIV Sexual Risk Practices of Drug Users, is related to the priority area of alcohol and other drugs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit, public and private organizations such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Women and minority investigators are encouraged to apply. Applications are encouraged from State and municipal governments with outreach units and/or State and municipal governments collaborating with university-based research units.

MECHANISM OF SUPPORT

This program announcement will use the National Institutes of Health (NIH) individual research project grant (R01) and FIRST (R29) award. In addition, the Interactive Research Project Grant (IRPG) program encourages the coordinated submission of related research project grants and, to a limited extent, FIRST (R29) awards may be used (see PA-93-078, NIH Guide, Vol. 22, No. 16, April 23, 1993). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant(s). Support will be provided for a period of up to five years (renewable for subsequent periods) for R01s, subject to continued availability of funds and progress achieved. FIRST (R29) awards must be for five years. Because the nature and scope of the research proposed in response to this program announcement may vary, it is anticipated that the size of an award will vary also. R29 awards are capped at \$350,000 over a five-year period.

RESEARCH OBJECTIVES

Summary

Since initiating its Cooperative Agreement (U01) for AIDS Community-Based Outreach/Intervention Research Program in 1990, the National Institute on Drug Abuse (NIDA) has been monitoring the HIV/AIDS epidemic in a population of out-of-treatment drug users across the country. Concurrently, other high-risk populations (including drug users) across the country have been monitored by the CDC. Behavioral change interventions are still the most promising prevention strategies available. All participating sites in NIDA's Cooperative Agreement program are participating in the development, implementation, and assessment of the effectiveness of a variety of community-based outreach intervention strategies to decrease viral transmission among IDUs and users of crack cocaine. The programs at CDC extend these efforts by including other high-risk populations.

Since these program began, many changes have occurred in community ecologies of risk (social and biological environments) related to HIV and drug use. A good deal of knowledge has accrued about preventing the spread of HIV through behavior change interventions (e.g., NIDA, 1993a, 1993b, 1993c; CDC, 1992, 1993). The focus of NIDA's behavioral interventions has been to facilitate IDUs to reduce their HIV risk behaviors (i.e., to reduce drug use and to increase use of sterile needles)--for which the interventions appear to have been met with success. There is less understanding about sexual risk taking and success in reducing risky sexual behaviors of injection drug users and crack smokers. For example, preliminary data from NIDA's Cooperative Agreement program (N=6161) show that approximately 75 percent of drug users interviewed reported they were sexually active in the last 30 days, with almost two-thirds reporting no condom use, and 50 percent reporting that they had engaged in more than 11 unprotected sexual acts with more than two partners. Because these practices did not change significantly, the risk of HIV continues to threaten the health and well-being of many drug-using persons and their sexual partners.

Findings from NIDA-sponsored and other research programs have demonstrated that a range of risk reduction interventions have been effective in facilitating at-risk injection drug users to enter into treatment, to reduce drug use, not to share needles, and/or to disinfect needles prior to re-using them. There is a compelling need to improve behavior change strategies to promote HIV related risk-reduction behaviors and help drug users who have made positive changes to maintain them and not relapse into greater risk. The challenge is to encourage drug users and their sexual partners to adopt and practice sexual behaviors that reduce their own risks and their partners' risks for acquiring or transmitting HIV infection. It is NIDA's intention to support the development, refinement, and evaluation of innovative interventions which retain a focus on reducing HIV related drug risks but that are particularly aimed at eliminating or reducing high risk sexual behavior in the following high-risk groups: (1) individuals or networks of sexually active male and female heterosexual/bisexual/gay injection drug users (IDUs), crack cocaine users, and/or poly-drug users; and (2) individuals or networks of male and female IDUs, crack cocaine users and poly-drug users who exchange sex for money or drugs for sex.

There is a need to improve behavior change strategies, particularly with respect to high-risk sexual practices, to reduce the further spread of HIV. NIDA wishes to expand current research efforts by phasing in and evaluating approaches that focus on reducing drug risks and are aimed at eliminating or reducing high risk sexual behavior. The complexity of sexual and drug-related risks should be acknowledged when developing appropriate interventions; that is, risks related to different drugs and multiple injection and disinfection practices in combination with a range of sexual behaviors including condom use, number of partners, and partners' HIV status. For strategies to be potentially effective and interpretable, they should be guided theoretically and should target sexual risks of drug users and/or their partners or networks of sexual and drug using companions or communities in which sexual behaviors or norms are enacted or maintained. Multiple level, multi-component intervention strategies are encouraged.

Program Description

It is important to understand the extent to which HIV prevention efforts are needed, already exist, or can be developed and can be effective for sexually active drug users at risk for HIV/AIDS. To this end, NIDA considers epidemiologic, ethnographic, and evaluation perspectives critical aspects of a multi-phase research effort. CDC also supports this approach. Baseline and longitudinal ethnographic, sociobehavioral and/or epidemiologic data are needed to identify and monitor the nature and extent of sexual and/or drug-related risk behaviors and their interactions, as well as the social settings or relationships that affect these behaviors. These data may be qualitative in nature, using ethnographic field observations and/or interviews, or they may derive from survey or other quantitative research. Baseline and longitudinal epidemiologic data are also needed on the serostatus of identifiable subgroups as a function of their risk characteristics. Investigators shall use these epidemiologic and ethnographic data to develop and refine appropriate sexual risk reduction interventions. Finally, controlled evaluation efforts are necessary to assess the effectiveness of prevention projects in eliminating or reducing sexual risk behavior and maintaining risk reduction behavior. Evaluation efforts may also be directed at modeling program effects on HIV serostatus. This program announcement can be viewed as complementing other Program Announcements, i.e., Drug Abuse Aspects of AIDS, PA-93-098; Partner Notification to HIV-Infected Drug Users, PA-93-111; and Research on Needle Hygiene and Needle Exchange Programs (NEP), PA-94-010 in which NIDA and CDC have collaborated.

Many previous HIV prevention studies have relied on behavioral change models that focus on the individual to change high-risk behavior or utilize generalized approaches to behavior that is not specific to sexual practices, gender differences, or cultural differences that influence the social context of risk taking. Applicants are encouraged to pay attention to social factors that influence changes in sexual practices and involve not only individual drug users but can also involve couples, groups, or communities in which sexual behaviors or norms are practiced and maintained. Prevention behavior change strategies can include, but need not be limited to: cognitive-behavioral skills training models, community/social norm change models, community mobilization efforts, diffusion of innovation models, and/or social networks approaches. Multidisciplinary perspectives are highly encouraged as is collaboration between researchers, populations at risk, and community-based organizations.

Phase I exploratory studies are sought to link macro (community, group, or network) and micro (individual) level factors influencing safer sex practices and reduce exposure to HIV by (1) identifying the nature and antecedents of sexual risk taking and change; (2) developing (or adapting) behavioral and/or social interaction models that are theoretically based and that are specifically designed to change high risk sexual practices (e.g., multiple partners, unprotected sex), antecedent cognitive and social conditions under which unsafe sex occurs (e.g., being high, lacking condoms), or relationship norms that maintain risky practices or affect negotiations over safe sex (e.g., casual versus steady partners, paying versus nonpaying partners); and (3) developing and pilot testing materials, interventions, strategies and methods of locating, engaging and retaining individuals or networks of crack smokers and injection drug users with elevated risk of transmitting HIV through unsafe sexual activities.

Interventions must take into account gender, race/ethnicity, sexual orientation, and/or risk behaviors and the social context in which the individual behaviors occur. We anticipate that multiple intervention strategies will be needed to take into account the behavioral heterogeneity among subpopulations at risk for HIV as well as the varying HIV seroprevalence of different communities. Applications should address such issues as gender-based outreach strategies, culturally appropriate HIV prevention strategies, and for behaviorally and socially specific interventions.

Phase II implementation and evaluation (quantitative and qualitative) will include interventions developed in Phase I. Evaluation will require research plans that include measurement of project implementation and compliance with protocol, estimates of sample size and periods of data collection, plans for minimizing attrition, strategies for client followup, specification of variables to be analyzed and measures to be used, statistical techniques to be employed, a discussion of the strengths and weaknesses of the analytic strategies, as well as a strategy for component analysis to identify the most and least effective parts of the intervention. In addition to measuring specific behaviors, norms, and other outcomes, the evaluation research must separately analyze intervention effects by specific subgroups who are at risk for HIV and must be sensitive to potential negative effects of the project. The final defining characteristic of Phase II research is the replicability of the selected intervention and the development of mechanisms for its operationalization at other sites. Attention must focus on the process of implementation and impact on the target populations to help us better understand the dynamics of behavior change.

It is critical to address methodological restrictions that can limit the contributions of Phase I or Phase II research to understanding HIV prevention. Much information can be gained if the interventions are theoretically grounded,

specific behaviors clearly identified and measured, design issues related to sampling, attrition, and followup specifically planned or controlled and intervention strategies are specific to the behaviors targeted for change.

It should be noted that the NIDA has developed a valid and reliable questionnaire (Risk Behavior Assessment) that may be modified and used to obtain drug and/or sexual risk information in the proposed study. Attention to using the most advanced strategies (new technologies for identifying, accessing, recruiting hidden populations and for data collection and transfer) are encouraged. As well, CDC has additional questionnaires. If the applicant plans to modify any currently used instrument, s/he should include an explanation of how validity and reliability will be assessed on the revised instrument.

Confidential voluntary HIV antibody testing must be made available to all study participants. The NIDA will work closely with each project to ensure the smooth operation of this requirement. PHS Policy requires that every effort be made to inform persons who are tested of their HIV results. Policy also requires that counseling and treatment be provided to all persons testing positive for HIV infection, and that retesting after six months be offered all persons testing negative. Detailed protocols for implementing HIV testing and pre- and post-test counseling have been previously described by NIDA and CDC and will be made available upon request.

As noted in this section, NIDA and CDC have collaborated, and will continue to collaborate, in the development and implementation of this program announcement.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard AIDS-related application deadlines as indicated in the application kit.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, Bethesda, MD 20892, telephone 301-594-7248. The title and number of the program announcement must be typed in Item 2a on the face page of the application.

The completed original and five permanent, legible copies of the PHS 398 form must be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications received under this program announcement will be assigned to an initial review group (IRG) in accordance with established PHS referral guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit in accordance with the standard NIH peer review procedures. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for further consideration by the Council may be considered for funding.

AWARD CRITERIA

Applications recommended for further consideration by an appropriate Advisory Council will be considered for funding on the basis of overall scientific, clinical and technical merit of the application as determined by peer review, program needs and balance, and availability of funds.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Richard Needle, Ph.D., M.P.H.
Community Research Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 9A-30
Rockville, MD 20857
Telephone: (301) 443-6720

Direct inquiries regarding fiscal matters to:

Gary Fleming, J.D., M.A.
Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of the Public Health Service Act, Section 301 and administered under PHS policies and Federal Regulations of Title 42 CFR 52 "Grants for Research Projects", Title 45 CFR Part 74 and 92, "Administration of Grants" and 45 CFR Part 46, "Protection of Human Subjects". Title 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Records" may be applicable to these awards. Title 42 Part 241(d) "Certificates of Confidentiality and Communicable Disease Reporting" will also apply. This program is not subject to the intergovernmental review requirements of Executive Order 12372.

References

National Institute on Drug Abuse 1993a The Behavioral Counseling Model for Injection Drug Users. Rockville, MD: The National Institute on Drug Abuse.

National Institute on Drug Abuse 1993b The Indigenous Leader Outreach Model. Rockville, MD: The National Institute on Drug Abuse.

National Institute on Drug Abuse 1993c The NIDA HIV Counseling and Education Intervention Model. Rockville, MD: The National Institute on Drug Abuse.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

5333 Westbard Avenue
Bethesda, MD 20816



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Vol. 23, No. 15
April 15, 1994

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THE NIH GUIDE FOR GRANTS AND CONTRACTS WILL NOT BE PUBLISHED ON APRIL 22, 1994. THE NEXT ISSUE OF THE NIH GUIDE WILL BE ON APRIL 29, 1994.

NOTICES

PUBLIC CONVOCATION---THE RESPONSIBLE CONDUCT OF SCIENCE

NIH GUIDE, Volume 23, Number 15, April 15, 1994

P.T.

National Academy of Sciences

Meeting Date: June 6 and 7, 1994

The National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine are committed to bringing matters of responsible conduct to the full attention of participants in the scientific and engineering enterprise. In pursuit of that goal, the Academy complex will hold a major public convocation on the conduct of science on June 6 and 7, 1994. The meeting will review progress made by government, universities, and other institutions in addressing matters related to the conduct of science and engineering, including the handling of allegations of misconduct and the creation of educational programs for new and established investigators. The meeting will also examine next steps to ensure that the highest standards of conduct in science are maintained. Participants in the convocation will include scientists and engineers, leaders of professional societies, research and university administrators, science educators, the media, and decisionmakers in the Administration, Congress, and industry.

Previous studies by panels formed by the Institute of Medicine and the Committee on Science, Engineering, and Public Policy have been supported by the National Institutes of Health and other Federal agencies, as well as private funds. The current requirement for instruction in the responsible conduct of research for trainees supported by NIH-funded institutional research training grants supports some of the recommendations from those panels.

INQUIRIES

To register or for more information, please contact:

Scott Spaulding
Commission on Life Sciences, NAS 351
National Academy of Sciences
2102 Constitution Avenue
Washington, DC 20418
Telephone: (202) 334-2233
FAX: (202) 334-1687
email: sspauldi@nas.edu

ADDITIONAL NIDA SUPPORT MECHANISM

NIH GUIDE, Volume 23, Number 15, April 15, 1994

P.T.

National Institute on Drug Abuse

Effective with the June 1, 1994, receipt date, the National Institute on Drug Abuse (NIDA) will accept applications utilizing the Cooperative Clinical Research (R10) mechanism. The R10 mechanism is used to support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between participating institutions and principal investigators and are usually conducted under established protocols.

INQUIRIES

Further information may be obtained from:

Ms. Eleanor Friedenberg
Office of Extramural Program Review
National Institute on Drug Abuse
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-2755

TERMS AND CONDITIONS OF AWARD FOR LARGE UNSOLICITED RESEARCH PROJECT APPLICATIONS FOR: CLINICAL TRIALS; PREVENTION, EDUCATION AND CONTROL INTERVENTIONS; AND EPIDEMIOLOGICAL STUDIES

NIH GUIDE, Volume 23, Number 15, April 15, 1994

P.T.

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) announces that any new or competing continuation investigator-initiated clinical trial, prevention, education, or control intervention, or epidemiological study in which direct costs exceed \$500,000 in any year will usually be awarded as a cooperative agreement (U01).

The \$500,000 direct costs limit applies when either (1) a study is to be conducted at one institution or (2) a study proposing multi-institutional collaborative arrangements is submitted as either subcontracts to a single application or as separate applications. For single applications, the dollar limit excludes indirect costs of any subcontracts that are reported as a direct cost on the application budget page summary. Separate U01 awards usually will be made for individual applications submitted concurrently by institutions proposing a study involving a coordinated research effort.

This policy is effective immediately with publication of this notice and covers all current pending unfunded applications as well as all future submissions.

The cooperative agreement is an assistance instrument similar in most ways to a grant. It differs in that, in addition to the standard stewardship role, an Institute extramural program director is expected to have a continuing substantive role in one or more scientific aspects of the study, in an assisting, not directing, relationship. The type and degree of such involvement should be appropriate to the specific cooperative agreement. The awardee will have lead responsibilities in all aspects of study, including any modification of study design, conduct of study, quality control, and analysis of results. The Institute program director may have assistance roles in one or more of those areas and will have a shared lead responsibility in facilitating interim data and safety monitoring.

In order to facilitate the above interactions, it will be necessary for awardees to plan for periodic (at least annual) meetings with NIAID staff in the Bethesda, MD area. Accordingly, applicants must request, and will be allowed, sufficient funds within the submitted budgets to accommodate expenses for participants at these meetings, as well as for expenses incurred in the conduct and monitoring of the study.

All awards made as cooperative agreements under the above circumstances will be subject to the applicable terms of award. Specific terms, conditions, and arbitration procedures pertaining to the scope and nature of the interaction between the NIAID and its awardees will be incorporated in the Notices of Award. It is anticipated that these terms and conditions will enhance the relationship between the National Institute of Allergy and Infectious Diseases and the principal investigator(s) and will facilitate the successful conduct and completion of the study. Therefore, applications falling under these guidelines, but not accepting the stated conditions, will not be considered for funding.

INQUIRIES

Potential applicants for research with these characteristics are strongly encouraged to contact the NIAID prior to making detailed plans or submitting their application(s). Questions regarding this notice and requests for a generic sample of terms and conditions of award may be directed to:

Director, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C20
Bethesda, MD 20892
Telephone: (301) 496-7291
FAX: (301) 402-0369

Potential applicants will be referred for further consultation to the appropriate NIAID Program and Grants Administration staff.

SMALL BUSINESS INNOVATION RESEARCH PROGRAM

NIH GUIDE, Volume 23, Number 15, April 15, 1994

P.T.

National Institutes of Health
Centers for Disease Control and Prevention
Food and Drug Administration

Application Receipt Date: August 15, December 15, 1994, April 15

Innovative technologies and methodologies fuel progress in biomedical and behavioral research and represent an increasingly important area of the economy. The Small Business Innovation Research (SBIR) program provides support for research and development (R&D) of new technologies and methodologies that have the potential to succeed as commercial products.

The purpose of this notice is to inform the public about the opportunities that the SBIR program offers to small business concerns as well as to scientists at research institutions, including colleges and universities.

The applicant organization must be a small business concern, and the primary employment of the principal investigator must be with the small business at the time of award and during the conduct of the proposed project. In accord with the intent of the SBIR program to increase private sector commercialization of innovations derived from federal research

and development, scientists at research institutions can play an important role in an SBIR project by serving as consultants and/or subcontractors to the small business concern. Normally, up to one-third of the Phase I budget may be spent on consultant and/or contractual costs, and up to one-half of the Phase II budget may be spent on such costs. In this manner, a small business concern with limited expertise and/or research facilities may benefit from teaming with a scientist at a research institution; for the scientist at a research institution, this team effort provides support for R&D not otherwise obtained.

Public Law 102-564, signed by the President October 28, 1992, requires the National Institutes of Health (NIH), Public Health Service, Department of Health and Human Services, and certain other federal agencies to reserve a specified amount of their extramural research or R&D budgets for an SBIR program. In fiscal year 1994, 1.5 percent of the extramural budget is reserved for the SBIR program, amounting to over \$125 million; in fiscal years 1995 and 1996, the allotment becomes 2.0 percent; and in fiscal years 1997 and beyond, the requirement will be 2.5 percent.

The SBIR program consists of the following three phases:

PHASE I: The objective of this phase is to determine the scientific and technical merit and feasibility and potential for commercialization of the proposed project and the quality of performance of the small business concern, before consideration of further federal support in Phase II.

PHASE II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.

PHASE III: The objective of this phase, where appropriate, is for the small business concern to pursue with non-SBIR funds the commercialization of the results of the research or R&D funded in Phases I and II.

The amount and period of support for SBIR awards are as follows:

PHASE I: Awards may not exceed \$100,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed six months.

PHASE II: Awards may not exceed \$750,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed two years, that is, generally, a two-year Phase II project may not cost more than \$750,000 for that project. A Phase I award must have been issued in order to apply for a Phase II award.

INQUIRIES

Eligibility requirements, definitions, application procedures, review considerations, application forms and instructions, and other pertinent information are contained in the OMNIBUS SOLICITATION OF THE PUBLIC HEALTH SERVICE FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) GRANT AND COOPERATIVE AGREEMENT APPLICATIONS, available from:

MTI, Inc.
13687 Baltimore Avenue
Laurel, MD 20707
Telephone: (301) 206-9385
FAX: (301) 206-9722

Following are contact points for discussion of program interests pertaining to awarding components participating in the SBIR grant program:

Dr. Miriam F. Kelty
National Institute on Aging
7201 Wisconsin Avenue, Room 2C-218
Bethesda, MD 20892
Telephone: (301) 496-9322
FAX: (301) 402-2945

Dr. Laurie Foudin
National Institute on Alcohol Abuse and Alcoholism
6000 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 443-4224
FAX: (301) 594-0673

Mr. Allan Czarra
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3C28
Bethesda, MD 20892
Telephone: (301) 496-7291
FAX: (301) 402-0369

Dr. Michael Lockshin
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 31, Room 4C32
Bethesda, MD 20892
Telephone: (301) 496-0802
FAX: (301) 480-6069

Dr. Steve Gordon
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407A
Bethesda, MD 20892
Telephone: (301) 594-9951
FAX: (301) 594-9673

Dr. Gladys M. Glenn
Cancer Biology and Diagnosis
National Cancer Institute
Executive Plaza North, Room 500
Bethesda, MD 20892
Telephone: (301) 496-5307
FAX: (301) 496-8656

Dr. Jack Gruber
Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-9740
FAX: (301) 496-2025

Dr. Ruthann M. Giusti
Cancer Treatment
National Cancer Institute
Building 31, Room 3A49
Bethesda, MD 20892
Telephone: (301) 496-6404
FAX: (301) 496-0826

Dr. Barry Portnoy
Cancer Prevention and Control
National Cancer Institute
Building 31, Room 10A49
Bethesda, MD 20892
Telephone: (301) 496-1071
FAX: (301) 496-9931

Ms. Connie Dresser
Interactive Multimedia Technologies for Cancer Prevention
National Cancer Institute
Executive Plaza North, Room 241
Bethesda, MD 0892
Telephone: (301) 496-0273
FAX: (301) 496-8675

Ms. Hildegard Topper
National Institute of Child Health and Human Development
Building 31, Room 2A03
Bethesda, MD 20892
Telephone: (301) 496-0104
FAX: (301) 402-1104

Ms. Jacqueline P. Downing
National Institute on Drug Abuse
Parklawn Building, Room 10A-55
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1056
FAX: (301) 443-6277

Dr. Daniel A. Sklare
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South Building, Suite 400-C
Bethesda, MD 20892
Telephone: (301) 496-1804
FAX: (301) 402-6251

Dr. Joyce A. Reese
National Institute of Dental Research
Westwood Building, Room 505
Bethesda, MD 20892
Telephone: (301) 594-7648
FAX: (301) 594-9720

Mr. John R. Garthune
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 637
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7594

Dr. Michael J. Galvin, Jr.
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-03
Research Triangle Park, NC 27709
Telephone: (919) 541-7825
FAX: (919) 541-2843

Dr. Ralph Helmsen
National Eye Institute
Executive Plaza South, Suite 350
Bethesda, MD 20892
Telephone: (301) 496-5301
FAX: (301) 402-0528

Dr. Michael R. Martin
National Institute of General Medical Sciences
Westwood Building, Room 936
Bethesda, MD 20892
Telephone: (301) 594-7753
FAX: (301) 594-7731

Dr. David Robinson
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 416
Bethesda, MD 20892
Telephone: (301) 496-5656
FAX: (301) 402-3508

Dr. John T. Watson
Devices and Technology Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 312A
Bethesda, MD 20892
Telephone: (301) 496-1586
FAX: (301) 480-6282

Dr. Thomas Blaszkowski
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 208A
Bethesda, MD 20892
Telephone: (301) 496-1841
FAX: (301) 496-0075

Dr. Carol Vreim
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 594-7430
FAX: (301) 594-7408

Dr. George Nemo
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 504
Bethesda, MD 20892
Telephone: (301) 496-1537
FAX: (301) 496-4843

Dr. Paul Didisheim
National Heart, Lung and Blood Institute
Federal Building, Room 312
Bethesda, MD 20892
Telephone: (301) 496-1586
FAX: (301) 480-6282

Michael F. Huerta, Ph.D.
Division of Neuroscience and Behavioral Science
National Institute of Mental Health
Parklawn Building, Room 11-103
Rockville, MD 20857
Telephone: (301) 443-5625
FAX: (301) 443-4822
Internet: HMI@CU.NIH.GOV

Dr. Judith Laughlin
National Institute of Nursing Research
Westwood Building, Room 738
Bethesda, MD 20892
Telephone: (301) 594-7493
FAX: (301) 594-7603

Mr. Edward Donohue
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1016
Bethesda, MD 20892
Telephone: (301) 496-4188
FAX: (301) 402-4370

Dr. William Heetderks
National Institute of Neurological Disorders and Stroke
Federal Building, Room 9C02
Bethesda, MD 20892
Telephone: (301) 496-5745
FAX: (301) 402-1501

Dr. Mary Ann Markwell
National Center for Research Resources
Westwood Building, Room 8A15
Bethesda, MD 20892
Telephone: (301) 594-7934
FAX: (301) 594-9187

Dr. Cynthia L. Pond
National Center for Research Resources
Westwood Building, Room 857
Bethesda, MD 20892
Telephone: (301) 594-7933
FAX: (301) 594-9149

Dr. Louise E. Ramm
National Center for Research Resources
Westwood Building, Room 854
Bethesda, MD 20892
Telephone: (301) 594-7906
FAX: (301) 594-9121

Dr. Dorothy D. Sogn
National Center for Research Resources
Westwood Building, Room 10A07
Bethesda, MD 20892
Telephone: (301) 594-7945
FAX: (301) 594-7929

Dr. Abraham Levy
National Center for Research Resources
Westwood Building, Room 10A11
Bethesda, MD 20892
Telephone: (301) 594-7947
FAX: (301) 594-9153

Dr. Richard DuBois
National Center for Research Resources
Westwood Building, Room 8A15
Bethesda, MD 20892
Telephone: (301) 594-7934
FAX: (301) 594-9187

Dr. Bettie J. Graham
Mapping Technology
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
E-Mail: Bettie_Graham@ocshost.nlm.nih.gov

Dr. Carol A. Dahl
Sequencing Technology
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
E-Mail: Carol_Dahl@occhost.nlm.nih.gov

Dr. David Benton
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National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
E-Mail: David_Benton@occhost.nlm.nih.gov

Dr. Eric T. Juengst
Ethical, Legal and Social Implications of Human Genome Research
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
FAX: (301) 480-2770
E-Mail: Eric_Juengst@occhost.nlm.nih.gov

Mr. Peter Clepper
National Library of Medicine
Building 38A, Room 5S518
Bethesda, MD 20894
Telephone: (301) 496-4221
FAX: (301) 402-0421

Dr. Roy Fleming
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mail Stop D30
Atlanta, GA 30333
Telephone: (404) 639-3343
FAX: (404) 639-2196

Mr. Ted Jones
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop F-36
Atlanta, GA 30341-3724
Telephone: (404) 488-4824
FAX: (404) 488-4422

Mr. Greg Jones
National Center for Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop C-19
Atlanta, GA 30333
Telephone: (404) 639-2434
FAX: (404) 639-1525

Victoria F. Westberg
National Center for Prevention Services
Center for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop E07
Atlanta, GA 30333
Telephone: (404) 639-1823
FAX: (404) 639-8601

Dr. Tom Sinks
Division of Environmental Hazards and Health Effects
National Center for Environmental Health
4770 Buford Highway NE, Mailstop F-28
Atlanta GA 30341-3724
Telephone: (404) 488-7350
FAX: (404) 488-7335

Dr. Richard A. Lasco
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway NE, Mailstop K-46
Atlanta, GA 30341-3724
Telephone: (404) 488-5428
FAX: (404) 488-5964

David E. Adcock
Public Health Practice Program Office
Centers for Disease Control and Prevention
1600 Clifton Road, NE, Mailstop E20
Atlanta, GA 30333
Telephone: (404) 639-1960
FAX: (404) 639-1989

Ms. Olia Hopkins
Division of Contracts and Grants Management
Food and Drug Administration
Parklawn Building, Room 320
Rockville, MD 20857
Telephone: (301) 443-6170
FAX: (301) 594-6577

NOTICES OF AVAILABILITY (RFPs AND RFAs)

PRECLINICAL TOXICOLOGY OF CHEMOPREVENTIVE AGENTS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFP AVAILABLE: NCI-CN-45001-05

P.T.

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Prevention and Control (DCPC), Chemoprevention Branch wishes to award Master Agreement contracts for the above study. The required services will be defined by Master Agreement Orders issued during the period of performance. It is estimated that four to five Master Agreement Orders will be issued per year pursuant to the Master Agreement contracts. This solicitation is the annual announcement to expand the current pool of MA Holders qualified to perform this type of work. A primary function of the chemoprevention program is the identification and evaluation of agents for possible utilization in clinical trials in humans. Candidate agents, whether from natural sources or synthesized, have been evaluated for anti-cancer efficacy in various screening tests. However, before a decision can be made as to their suitability for the Phases I clinical trials in humans, they must be evaluated for toxicity in animals. The basic objectives of this project will be to evaluate the acute, subacute/subchronic and chronic toxicity of designated agents. These studies will be performed in animals (rodents and dogs) and will include conventional multi-generation teratogenicity studies. The agents would be given primarily by the oral route. A summary of the tasks required in the project are as follows: TASK I - Perform acute toxicity, pilot dose range finding, and 13-week subchronic toxicity in rats and dogs by the oral route. Include where appropriate, complete gross necropsies, histopathological examinations, and clinical laboratory studies. TASK II - Develop a protocol for a pharmacokinetic profile for each investigational agent. The protocol and profile may build upon published data and data provided by the manufacturer of the agent or NCI staff. Additional studies necessary to complete the pharmacokinetic profiles for the rat and dog shall be performed by the Contractor. Pharmacokinetic studies will provide parameters of absorption blood concentration-time profiles, distribution, and excretion. Data on tissue concentration to the test agent, determined as part of the toxicology testing shall contribute to the pharmacokinetic profile. Information on major metabolites shall be included in order to provide as complete a picture as possible of the overall distribution and fate of the test agent. Appropriate modeling shall be applied to determine probable pattern of distribution and absorption and half-life information necessary to plan the 90-day rat and dog toxicology studies. TASK III - Develop and perform teratogenicity studies on chemopreventive agents that have the prospect of being administered to women of childbearing potential. These will be the standard segment I, II, and III studies as described in the Guidelines for Reproduction Studies for Safety Evaluation of Drugs for Human Use, available from the Contract Specialist, upon request.

For efficiency, the male rats from the 3-month oral study may be used to initiate the male-related reproductive toxicity studies. TASK IV-Perform chronic one-year oral toxicity in rats and dogs. Clinical laboratory studies and gross and microscopic necropsy findings are to be included. Suitable facilities and equipment appropriate to accomplish tasks should be available. Animal-holding facilities for dogs must be provided with adequate environmental containment. Offerors are to comply with the NIH Guide for Care and Use of Laboratory Animals. Facility must have design and maintenance capability to meet chemical and biological control; must comply with NCI carcinogens and handling standards; must comply with federal and state occupational health and environmental laws and regulations. On-site data handling (computer), chemical, and pathological facilities and equipment should be available. Must comply with requirements set forth in the FDA Good Laboratory Practice Regulations. The period of performance of the Master Agreement pool will be approximately three years. The Master Agreement Announcement/Request for Proposal (MAA/RFP) will be available on approximately April 29, 1994. The due date for proposals is approximately June 30, 1994.

INQUIRIES

Copies of the MAA/RFP NCI-CN-45001-05 may be obtained by sending a written request to:

Mr. Gary P. Topper
Prevention and Control Contracts Section
National Cancer Institute
Executive Plaza South, Suite 635
Bethesda, MD 20892
Telephone: (301) 496-8603
No collect calls will be accepted

EXPLORATORY CENTERS FOR ALTERNATIVE MEDICINE RESEARCH

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA AVAILABLE: OD-94-004

P.T.

Office of Alternative Medicine

Letter of Intent Receipt Date: May 9, 1994

Application Receipt Date: June 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Office of Alternative Medicine invites applications that describe a plan for providing technical, clinical/scientific/assistance to Alternative Medicine (AM) clinicians/researchers as they develop their clinical databases.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," an initiative for setting national health policy and priorities. Although "Healthy People 2000" does not currently specify an AM objective, this RFA includes priority areas within the "Healthy People 2000" objectives that involve alternative medical health care. Applicants may obtain a copy of "Health People 2000" (Full Report: Stock No. 017001-00474-0) or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and not-for-profit organizations, public and private organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, Federally recognized Indian Tribal organizations, and eligible agencies of the Federal government. Applications may include foreign components, but foreign organizations are not eligible to apply.

MECHANISM OF SUPPORT

The mechanism of support is the Resource-Related Research Projects mechanism (U24). Under the cooperative agreement mechanism, OAM anticipates substantial programmatic involvement with the awardee in a partner role during performance of the project. In general, allowable costs must be consistent with PHS policy and recommended by peer reviewers. These costs can include, but are not limited to, personnel costs, supplies, consultant costs, equipment, travel, sub-contractual and other when appropriate.

FUNDS AVAILABLE

The estimated funds available (total costs) for this fiscal year will be approximately \$1.8 million. It is anticipated that two or three awards will be made. Length of support will be four years.

RESEARCH OBJECTIVES

The Office of Alternative Medicine plans to accomplish its objective to investigate and validate alternative therapies by developing exploratory centers. Within these centers the potential will exist to support planning for new interdisciplinary programs involving experienced investigators from conventional medicine with clinicians and investigators from Alternative Medicine. These centers should be able to provide clinical/scientific/technical assistance to alternative medicine clinicians who may have potentially useful accumulations of patient data that could be evaluated for treatment outcome. It will be important that the research faculty at these centers have expertise in broad areas such as biostatistics, computer processing, data management, and protocol design. Assistance is to be provided to alternative medicine clinicians/researchers for the evaluation of their retrospective clinical data. Additionally, through a peer review process which will be established by the centers, small prospective pilot studies will be started. The ultimate goal is to establish if selected "alternative therapies" have potential for further evaluation through more extensive clinical trials research.

Program areas that are to be developed and subsequently evaluated regarding treatment efficacy can include: (1) Nutrition, Diet and Lifestyle/Behavioral Health Changes; (2) Mind/Body Control Therapies; (3) Traditional and Ethnomedicine Therapies; (4) Structural Manipulations and Energetic Therapies; (5) Pharmacological and Biological Therapies; (6) Bioelectromagnetic Therapies;

Each center should, during the entire cooperative agreement period, evaluate the application of three of the above program areas by integrating them into one of the following center themes: (a) cancer; or (b) pain; or (c) other (disease or symptom other than cancer or pain).

APPLICATION PROCEDURES

Applications must be received by June 15, 1994. To apply for an Exploratory Center Cooperative agreement award, applicants are to use the PHS research grant application form PHS 398 (rev. 9/91) available from the applicant institution's office of sponsored research. Application forms can also be obtained from the Office of Grants Information

Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applicants are encouraged to submit a letter of intent by May 9, 1994 to the program person listed in the Inquires section. Completed application receipt date will be June 15, 1994.

The title and number of the RFA must be typed in Section 2a on the face page of the application. The signed, typewritten original of the application and three signed, exact clear and single-sided photocopies, and the completed Checklist must be sent in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

- o Scientific and technical merit of the proposed approaches for conducting the project.
- o Qualifications and clinical/research training and experience of the Principal Investigator and staff;
- o Demonstration that the appropriate AM community linkages exist.
- o Availability of resources necessary to perform research assistance activities.
- o Appropriateness of the proposed budget.

AWARD CRITERIA

The anticipated date of award is September 30, 1994. Factors that will be taken into consideration in making awards include the scientific merit of the proposed application as evidenced by the priority score and the availability of funds.

INQUIRIES

The above description of the RFA guidelines is an abbreviation of a more extensive RFA that must be requested from the program administrator listed below. Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Applicants are urged to contact the program administrator, as soon as they receive approval from their institution to apply for this award.

Direct inquiries regarding programmatic issues to:

John Spencer, Ph.D
Office of Alternative Medicine
National Institutes of Health
6120 Executive Boulevard, Suite 450
Rockville, MD 20892-9904
Telephone: (301) 402-2466
FAX: (301) 402-4741

AUTHORITY AND REGULATIONS

This Program is described in the Catalog of Federal Domestic Assistance No. 93.213, Research and Training in Alternative Medicine. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MULTI-SITE STUDY OF MENTAL HEALTH SERVICE USE, NEED, OUTCOMES, AND COSTS IN CHILD AND ADOLESCENT POPULATIONS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA AVAILABLE: MH-94-009

P.T.

National Institute of Mental Health

Letter of Intent Receipt Date: May 1, 1994
Application Receipt Date: July 12, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Mental Health (NIMH) invites cooperative agreement applications for a five-year study of child and adolescent mental health services. Applications are invited for two types of studies.

One type involves multi-site, collaborative, longitudinal, community-level studies of the types and patterns of mental health service used by children and adolescents, ages 4 to 17, the extent of unmet need for services, and the ways in which the organization and financing of services influence access to, use of, and outcomes of mental health services. The major goal of this study is to encourage investigations of the following overarching types of questions: How do

community factors (poverty levels, rates of unemployment, rural/urban), service system variables (range, degree of coordination, types of inter-relationships), economic constraints (methods of financing), cultural influences (degree of acculturation, contextual factors), and family factors (roles, structures, supports, functioning) influence the need, access, use, and outcomes of mental health services across several service sectors for children and adolescents? To what extent are children's mental health needs enduring or transient? What is the impact of services on the relative persistence of children's mental health needs? With these questions providing a broad conceptual framework, applications are invited for studies in community sites by independent teams of investigators who will work together to develop a common study protocol.

The other type of study involves a national epidemiological survey to address issues related to the prevalence and incidence of specific mental disorders among children and adolescents, ages 4 to 17, rates of mental health service utilization across major service sectors, and costs and financing of care. In view of the scale and complexity of the research tasks involved, applications to conduct both types of studies concurrently are not encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Multi-site Study of Mental Health Service Use, Need, Outcomes, and Costs in Child and Adolescent Populations, is related to the priority areas of mental disorders and suicide in children and adolescents. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Application may be submitted by domestic public and private, for-profit and non-profit institution, such as a university, college, community agency, State and local governments, and eligible agencies of the Federal government. Eligibility under this program is limited to applications from institutions of the United States, its territories and commonwealths. Minority and women investigators are encouraged to apply.

MECHANISM OF SUPPORT

A cooperative agreement mechanism (U01) will be used for this study program. The NIMH will work jointly with the awardees in a partnership role, to support, coordinate, and facilitate the awardees' activities. Direction and principal responsibility for the conduct and implementation of the study will rest with the awardees. Details of the responsibilities, relationships, and governance of the study are discussed in the RFA under the section "Terms and Conditions of the Award."

FUNDS AVAILABLE

It is estimated that up to \$7 million in total costs will be available for the first year of support. The exact amount of funding available will depend on the quality of applications and program priorities at the time of the award. It is anticipated that five to seven awards will be made in September 1994. The total project period is five years.

RESEARCH OBJECTIVES

Background. Research to date on service use by children and adolescents with mental health problems has shown that multiple service sectors are often involved: general health, education, child welfare, juvenile justice, substance abuse, and mental health. Community surveys have shown that between 6 and 16 percent of children and adolescents with diagnosable mental disorders have received some type of mental health service in the past year. However, much is unknown about both the children and adolescents who receive care and those who do not.

For those who do receive mental health services, there is limited scientific knowledge about the care they are receiving; the patterns of their service use and pathways into services; the factors influencing access to and sources of care; and the costs and quality of care. For those who do not receive mental health services, there is little scientific understanding of the social, cultural, financial, or geographic barriers experienced by the children and their parents; the alternative sources of care used; and the consequences in either the short or long term of lack of specific types of care.

To obtain a more precise scientific understanding of the scope of services available to children and adolescents and of the effectiveness of the services that exist, a multi-site community study is needed. In addition, to determine the level of unmet need for services across the United States, a prevalence study of mental disorders is necessary.

The Community Study

Objectives and Scope. This study program will be the first major multisite collaborative study to investigate the ways in which multiple factors influence child and adolescent use of mental health services and the outcomes associated with the use and non-use of mental health services. Through use of a common study protocol, to be developed and agreed upon by investigators participating in the research, the study will make it possible to pool data from different community sites and compare community and national data. The main questions in this study program concern the influence of multiple community, service system (including organizational and financial), cultural, and family variables on child and adolescent service use and outcomes of care.

The National Survey

The purpose of the National Survey is to provide estimates of the prevalence and incidence of specific mental disorders and behavioral problems among children and adolescents, degree of associated functioning impairment, rates of mental health service utilization, and costs of care for children and adolescents with mental disorders. It is anticipated that one site may be selected to conduct the national survey. The selected site will be expected to work with the community sites as part of the multisite collaborative research team.

SPECIAL REQUIREMENTS

To assist in the development of collaborative activities among the selected sites, applicants should consider several issues. These are discussed in the complete RFA.

STUDY POPULATIONS

INCLUSION OF FEMALES AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Females and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are strongly encouraged to submit, by May 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the study type (i.e., community study or national survey), the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. The letter of intent is to be sent to Dr. Kimberly Hoagwood at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). Application kits containing the necessary forms may be obtained from offices of sponsored research at most universities, colleges, medical schools, and other major research facilities and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

The number and the title of this RFA must be typed in item 2a on the face page of the PHS 398 application form; the YES box must also be marked. Applicants must submit, in one package, a signed original of the application, including the Checklist, and four signed copies to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications that are complete and responsive to this RFA may be subjected to a preliminary evaluation by a peer review group, convened by the NIMH, to determine their scientific merit (triage); the NIMH will withdraw from further consideration applications judged to be noncompetitive and notify the principal investigator or program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by an initial review group (IRG) consisting primarily of non-Federal experts, convened by the NIMH. Final review is by the Mental Health Advisory Council. Notification of the review outcome will be sent to the applicant by the NIMH. Only applications recommended by Council may be considered for funding. See RFA for a description of criteria that will be used in the review.

AWARD CRITERIA

Factors considered in determining which research applications will be funded are: scientific and technical merit, Council recommendations, responsiveness to the goals of this RFA, significance of the topic under study to NIMH priorities, program balance, public health significance, and availability of funds. Other criteria are indicated in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Kimberly Hoagwood, Ph.D.
Child and Adolescent Services Research Program
National Institute of Mental Health
5600 Fishers Lane, Room 10C-06
Rockville, MD 20857
Telephone: (301) 443-4233
FAX: (301) 443-4045
E mail: KHOAGWOO@AOAMH2.SSW.DHHS.GOV

Direct inquiries regarding grants management issues to:

Diana Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic assistance No. 93-242. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410) as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 as implemented through Department of Health and Human Services regulations at 45 CFR part 100 or Health Systems Agency review.

BASIC RESEARCH IN HUMAN TUBERCULOSIS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA AVAILABLE: AI-94-022

P.T.,

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: May 20, 1994

Application Receipt Date: July 14, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA). IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

APPLICATIONS IN RESPONSE TO THIS RFA MUST BE PREPARED USING A MODIFIED (ABBREVIATED) GRANT APPLICATION FORMAT; SPECIFIC INSTRUCTIONS ARE IN THE COMPLETE RFA.

PURPOSE

The Respiratory Diseases Branch of the Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (NIAID) invites applications to conduct innovative basic research to elucidate the basic biology, immunology, epidemiology, and pathogenic mechanisms of infection with *Mycobacterium tuberculosis*. To better understand tuberculosis epidemiology, progression, treatment, and control, the NIAID wishes to expand research in these areas with the goals of developing rational strategies for vaccine and drug development, and improving the diagnosis, treatment, and prevention of this disease.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Basic Research in Human Tuberculosis, is related to the priority areas of immunity, infectious diseases, and HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-782-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private institutions, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply for First Independent Research Support and Transition (FIRST) (R29) Awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The mechanisms of support will be the individual research project (R01) grant and the FIRST (R29) award. The total project period may not exceed five years for R01s and is five years for R29s.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for all awards under this RFA will be \$3,500,000. In Fiscal Year 1995, the NIAID plans to fund approximately 15 R01s/R29s. Applications may not request more than four percent annual inflationary increases for future years. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIAID, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

Background

On April 23, 1993, the World Health Organization declared tuberculosis a global public health emergency, an opprobrium never accorded another disease. Once believed by health officials to be contained, tuberculosis is now recognized as out of control in many parts of the world. In the United States an estimated 15 million people are currently infected with tuberculosis. Cases increased 20 percent during the period 1985 to 1992, and in 1992, 26,678 cases of active tuberculosis were reported to the CDC. This trend continues. Persons most likely to suffer the disease include HIV-infected persons, the homeless, chronic alcohol or drug-abusers, those living in long-term care facilities such as nursing homes and jails, and especially certain minorities.

The increase of tuberculosis cases in developed countries is attributed to several causes. The most important of these include the link between tuberculosis and HIV infection and the emergence of drug-resistant strains of *Mycobacterium tuberculosis*. Tuberculosis is the only AIDS-associated infection readily transmitted to non-HIV-infected persons. The tuberculosis crisis is intensified by the emergence of disease caused by multidrug-resistant organisms. These strains may result in an essentially incurable form of the disease, capable of spread by casual contact. Treatment of MDR-TB infections is difficult, expensive, and often unsuccessful. The resurgence of tuberculosis poses special problems for health care workers, social workers, prison personnel, and other contacts at risk.

The challenge for basic researchers, clinicians, and health officials interested in tuberculosis is to apply the advances in molecular biology, genetics, immunology, and epidemiology to those problems left unexplained when research interest in tuberculosis waned. The primary goals of these efforts include the development of an effective vaccine and progress toward improved antibiotic therapies to assist in prevention and treatment of active disease. These challenges require research in a variety of areas.

Research Objectives and Scope

The objective of this RFA is to encourage established investigators and investigators new to TB research to pursue innovative research in the following representative, but not all-encompassing or limiting, areas:

- o Epidemiology of tuberculosis infection, reactivation, and reinfection to improve understanding of disease transmission
- o Improved understanding of genetic mechanisms (recombination, repair and replication) and of the molecular basis by which *Mycobacterium tuberculosis* invades target cells, avoids host defense mechanisms, causes tissue damage, and ultimately kills the host
- o *Mycobacterium tuberculosis* antigens: identification of antigens expressed within infected macrophages, and their role in enhanced cell-mediated immunity and reduced delayed-type hypersensitivity
- o Development of a human in vitro model system that can predict, or help to identify, potentially protective *Mycobacterium tuberculosis* antigens
- o Immunologic mechanisms and other host factors that contribute to development of primary tuberculosis
- o Immune modulators in regulation of T-cell response in protection, granuloma formation, and macrophage *Mycobacterium tuberculosis* interactions
- o Design of drugs for latent *Mycobacterium tuberculosis* infections
- o Characterization of molecular or metabolic targets with potential for design of new treatment and/or prophylaxis agents.
- o Preparation of attenuated strains of *Mycobacterium tuberculosis* as candidate vaccines

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the new "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details. Copies of these Guidelines may be obtained from Dr. Foulds at the address listed under INQUIRIES.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 20, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, and the number and title of this RFA. Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of subsequent applications, the information that it contains allows NIAID staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 09/91) as modified by the special instructions in the RFA. Specifically, some sections are not required and the page limits for applications are modified. Application forms may be obtained from the institution's office of sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by July 14, 1994.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number AI-94-022 and the words "Basic Research in Human Tuberculosis" must be typed in.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID for responsiveness to this RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration. Those considered complete and responsive may be subjected to a triage review by an NIAID peer review group to determine their scientific merit relative to the other applications. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant. Those applications judged to be

competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee convened by the NIAID. A second level of review will be provided by the NIAID Advisory Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Requests for the RFA and the "NIH GUIDELINES FOR INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH," as well as inquiries regarding programmatic issues may be directed to:

Dr. John Foulds
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3B10
Bethesda, MD 20892
Telephone: (301) 496-5305
FAX: (301) 496-8030
E-Mail: jf32v@nih.gov or
E-Mail (alternate): Jfoulds@exec.niaid.pc.niaid.nih.gov

Direct inquiries regarding review issues and address the letter of intent to:

Olivia Preble, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C19
Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638
E-Mail: op2t@nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Catherine Walker
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B32
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

Letter of Intent Receipt Date: May 20, 1994
Application Receipt Date: July 14, 1994
Scientific Review Date: October 1994
Advisory Council Date: February 1995
Earliest Award Date: April 1, 1995

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.855 - Immunology, Allergy and Transplantation Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78- 410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL COOPERATIVE VACCINE DEVELOPMENT GROUPS FOR AIDS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA AVAILABLE: AI-94-015

P.T.

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: May 31, 1994

Application Receipt Date: August 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRES" BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of an RFA for funding National Cooperative Vaccine Development Groups for AIDS (NCVDGs). It is the purpose of this RFA to invite applications aimed at the conceptualization, development, and evaluation of vaccines designed to effectively prevent the Acquired Immunodeficiency Syndrome (AIDS). This research should stress creative, novel approaches to the development of effective AIDS vaccines and should have the capacity to rapidly translate these concepts into improved candidate vaccines. The NCVDG can be focused in one or more vaccine areas and may pursue studies of HIV-based vaccines or studies of relevant model viruses (e.g., the Simian Immunodeficiency Viruses). The Group must possess the expertise necessary to conduct adequate evaluation of the proposed approach(s) in preclinical situations. An NCVDG must form a cohesive team and is encouraged to include scientists from a combination of academic, non-profit research, and commercial organizations. Applications that include research projects from the private sector (e.g., pharmaceutical, chemical, or biotechnological companies) are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000", a PHS-led national activity for setting priority areas. This RFA, National Cooperative Vaccine Development Groups for AIDS (NCVDGs), is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, companies, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Awards will be made as multiproject cooperative agreements (U19s). The multiproject cooperative agreement (U19) is an "assistance" mechanism (rather than an "acquisition" mechanism) in which substantial NIAID programmatic involvement with the recipient during the performance of the planned activity is anticipated. Essential elements of the U19 mechanism include: (1) a minimum of three inter-related research projects around a central theme; (2) collaborative efforts and interaction among independent projects and their investigators to achieve a common goal; (3) a single Principal Investigator who will be scientifically and financially responsible for the use and disposition of funds awarded; and (4) support provided, as necessary, for "Core" resources or facilities, each of which is expected to be utilized by at least two research projects in order to facilitate the research effort. Under the cooperative agreement, the NIH purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the award recipient in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity.

While the number of applications cannot be determined, both new and competitive renewal applications are anticipated. The total project period for applications submitted in response to this RFA may not exceed four years. All policies and requirements that govern the grant program of the PHS, and the NIH apply.

FUNDS AVAILABLE

Because of the nature and scope of this RFA, the NIAID anticipates making two awards, based on highest program priorities, for project periods up to four years. The NIAID has set aside \$1.6 million total (direct and indirect) costs for first year funding. This level of support is dependent on the receipt of a sufficient number and diversity of applications of high scientific competitiveness. Although this program is provided for in the financial plans of the NIAID, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Background

The National Cooperative Vaccine Development Groups for Acquired Immunodeficiency Syndrome (NCVDGs) will provide assistance to talented scientists to interact, with NIAID support, as a unit to carry out the research essential to realize project objectives. An NCVDG may be composed of scientists from academic and/or non-profit research institutions, and commercial organizations. An NCVDG must be a cohesive team with the Principal Investigator and all Project Leaders working together. The Principal Investigators of the NCVDG Network will hold two to three meetings per

year to communicate and coordinate their research efforts. Strong team work and interactions are necessary to accomplish NCVVG research goals. The NIAID has awarded thirteen NCVVGs; two have already expired and four are expiring in fiscal year 1993. The purpose of this 1994 recompetition is to maintain the total NCVVG network at ten groups aimed at facilitating and accelerating efforts in AIDS vaccine development. A listing of the current NCVVGs is available upon request.

Goals and Scope

The principal goal of the NCVVGs is the conceptualization, development, and evaluation of vaccines designed to effectively prevent AIDS. This research can focus on HIV or other lentiviruses (e.g., Simian Immunodeficiency Viruses (SIV)) that are appropriate models for AIDS vaccine development and that may involve animal model studies of vaccine immunogenicity and efficacy.

Applications for funding as an NCVVG should stress creative, novel approaches to the development of effective AIDS vaccines and may emphasize one or more of the general approaches outlined below. It is important to have the ability to perform immunological analyses to evaluate the work being done and to network with the NIAID Adjuvant Group and the NIAID Collaborative Mucosal Immunity Groups. Since the currently funded NCVVGs are also pursuing research in many of these areas, potential applicants are strongly encouraged to contact program staff to determine if their proposed studies address vaccine strategies not currently being funded. Applications for research on novel vaccine vectors, immunogen processing and presentation, mucosal immunity, nucleic acid vaccines, and creative methods to enhance immunogenicity are encouraged.

Approaches may include, but are not limited to:

1. live attenuated vaccines;
2. whole inactivated vaccines;
3. recombinant proteins or protein fragments;
4. novel recombinant viruses or other vectors (e.g., yeast Ty elements, hepatitis B virus, salmonella);
5. synthetic peptides;
6. combination approaches;
7. DNA immunization.
8. adaptation of existing pediatric vaccines to express HIV/SIV antigens

Applications should address all aspects of the process from basic research through subsequent developmental studies, scale-up and production, evaluation in laboratory animals, protection of appropriate species from infection or disease following virulent challenge, and other considerations that relate to the acceptability and utility of candidate vaccines. Results from proposed research should be used to identify and develop new potential vaccines worthy of evaluation in Phase I human clinical trials.

SPECIAL REQUIREMENTS

Applications seeking funding as an NCVVG for AIDS must be from a Group and must meet the special requirements as outlined in the RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by May 31, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of Project Leaders and other key personnel and their participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of expected applications. It allows NIAID staff to estimate the potential workload for reviewers and to avoid possible conflict of interest in the review process. The letter of intent is to be sent to Dr. Dianne Tingley at the address listed under INQUIRES.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), the standard application form for research grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248.

Applications not received by August 19, 1994 will be returned without review.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID staff to determine responsiveness to this RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration or review. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant and the institutional business official. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee convened by the NIAID. A second level of review will be provided by the NIAID National Advisory Council.

INQUIRIES

It is essential that prospective applicants obtain a copy of the RFA before preparing an application. Written and telephone requests for the RFA and the opportunity to clarify issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic or scientific issues to:

Dr. Alan M. Schultz
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2B-01
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8200

Direct inquiries regarding fiscal matters to:

Ms. Carol Alderson
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B27
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

Direct inquiries concerning review issues and address the letter of intent to:

Dr. Dianne Tingley
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C-16
Bethesda, MD 20892
Telephone: (301) 496-0818

Schedule

Letter of Intent Receipt Date: May 31, 1994
Application Receipt Date: August 19, 1994
Scientific Review Date: November 1994
Council Meeting Date: February 1995
Earliest Award Date: April 1995

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergy and Transplantation Research. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL MULTIPURPOSE RESEARCH AND TRAINING CENTERS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA AVAILABLE: DC-94-002

P.T.

National Institute on Deafness and Other Communication Disorders

Letter of Intent Receipt Date: June 10, 1994
Application Receipt Date: October 20, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute on Deafness and Other Communication Disorders (NIDCD) announces its intent to designate and support a limited number of National Multi-purpose Research and Training Centers for the multidisciplinary study of hearing and other communication processes. The goal of these Centers is the support of basic and clinical research; research training; continuing education for health professionals; and dissemination of information to the general public, in one or more of the NIDCD program areas. A National Multipurpose Research and Training Center is a national resource and is dedicated to working with the NIDCD in furthering the goals of the NIDCD, through a multidisciplinary, coordinated approach involving basic and clinical research, research training, continuing education for health care professionals, and dissemination of information to the public. A Center may focus on one or more of the major scientific areas of the NIDCD (hearing, balance, smell, taste, voice, speech, and language), but each of the components, including the research training and continuing education components, must relate to the central theme of the Center. All of the components must be of high quality, as judged by the NIH standards for biomedical and behavioral research excellence.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Multipurpose Research and Training Centers, is related to the priority area of education and community-based programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-11474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-11473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Any of the following domestic organizations are eligible to apply: non-profit institutions of higher education; other non-profit and for-profit organizations; state and local governments and their agencies; and authorized Federal agencies. Domestic institutions may include foreign components. Holding a currently funded National Multipurpose Research and Training Center, Program Project (P01), Clinical Research Center Grant (P50) or Institutional Training Grant (T32) does not preclude an organization from applying.

MECHANISM OF SUPPORT

National Multipurpose Research and Training Centers will be funded through the Comprehensive Center grant mechanism (P60). Competitive supplemental applications to the Center grant are not allowed.

FUNDS AVAILABLE

According to current budgetary predictions, it is anticipated that up to five awards will be made, some in FY 1995 and some in FY 1996. Five years of support must be requested at a direct cost not to exceed one million dollars for the first year. The award of National Multipurpose Research and Training Center grants is contingent upon the assessment of the applications by peer review and the allocation of appropriated funds for this purpose. Funding for Center grants beyond the initial period will be subject to competitive renewal.

RESEARCH OBJECTIVES

The purpose of this current RFA is to request applications for: (1) new National Multipurpose Research and Training Centers and, (2) the continuation of existing National Multipurpose Research and Training Centers. The purpose of the National Multipurpose Research and Training Centers is to enhance research in hearing and other communication processes. The Centers will stimulate important areas of basic and clinical research. by utilizing a multidisciplinary approach, these Centers will provide broad-based solutions to complex human communication problems.

Each Center must have research activity in the basic sciences. This activity may include disciplines such as molecular biology and genetics, cellular biology, neurochemistry, immunology, microbiology, epidemiology, and biomedical engineering. Ideally, the Center will draw together the multidisciplinary resources of the institution to investigate the etiology, diagnosis, treatment, rehabilitation, and prevention of specific communication impairments. The Center may also undertake/conduct population-based studies and genetic studies related to the specific communication disorder(s) being studied.

Clinical investigations will focus on the etiology, diagnosis, treatment, rehabilitation, and/or prevention of specific impairments. Suggested areas may include: deafness and hearing disorders in children; presbycusis; balance or vestibular disorders, particularly in the elderly; aphasia; stuttering; and disorders of smell and taste. Clinical research activities may also include studies of implantable biomaterials and biomechanical diagnostic and assistive devices. Each Center should seek to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk for developing the particular disorder(s) that is the focus of the research program of the Center.

The Center will provide research training opportunities, thereby strengthening the quality and increasing the number of investigators in communication sciences. Medical and surgical residents, pre- and post-doctoral fellows, and students will benefit from research training in a multidisciplinary environment. Special emphasis may be placed on independent investigators who apply such methods as immunology or molecular biology to problems within the communication sciences. In addition, research training for clinical professionals such as otolaryngologists, speech-language pathologists, audiologists, and chemosensory psychophysicists is encouraged.

Each Center will develop continuing education programs for physicians and other health care professionals who provide care to patients with disorder(s) within the research focus of the Center. Education programs should include information on current methods of early diagnosis and treatment, as well as seek to disseminate the results of research activities.

Centers will also include programs for the dissemination of information to the general public on the importance of early detection of the particular disorders or impairments under study, of seeking prompt treatment, rehabilitation, and when indicated, of following an appropriate therapeutic regimen. When appropriate, these public information programs may also focus on the importance of avoiding exposure to noise or other environmental toxic agents that may affect the impairments under examination.

It is essential that the continuing education and information dissemination programs develop and implement evaluation instruments/tools that measure the effectiveness of these activities so that useful techniques may be shared with other Centers and health care providers. The NIDCD expects each Center to develop its own program in accordance with local strengths, talents, interests, and resources. Each RTC must be willing to cooperate actively with other Centers awarded under this and other NIDCD Center solicitations; collaboration is encouraged.

The NIDCD expects each Center to develop an External Advisory Committee. These committees should provide direction, evaluation, and input to RTC staff on a regular basis. NIDCD Health Scientist Administrators (HSAs) will coordinate plans for any special activities focusing on issues of mutual interest to the Institute and the RTCs. These may include training, information techniques, or continuing education, for example. NIDCD HSAs will be responsible for evaluating progress. To foster cooperation among Centers, the Center Directors will meet with NIDCD staff at least once a year to review progress and coordinate similar activities.

SPECIAL REQUIREMENTS

Applicants for the "National Multipurpose Research and Training Centers" Grant Award must propose a program that includes basic and clinical research, research training, continuing education, and information dissemination. In addition, where appropriate, the Centers may pursue additional activities, as outlined in the RFA. The Center may be a consortium of institutions, organizations, and medical facilities. Budget guidelines are also described in the RFA.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

To facilitate NIDCD planning, applicants are requested to submit a letter of intent by June 10, 1994. The letter should include a descriptive title, names of investigators who might be involved, and names of any participants outside the applicant institution. The NIDCD requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, therefore, does not acknowledge their receipt. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, nor is it a requirement.

The letter of intent is to be sent to Dr. Ralph F. Naunton at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the form PHS 398 (rev. 9/91). The training component must be submitted in accordance with the section for Institutional National Research Service Awards. This form is available in the applicant institution's office of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449 Bethesda, MD 20892, telephone 301/594-7248.

Applicants should utilize the instructions described in the document "Application Guidelines: National Multipurpose Research and Training Centers (RTC)," available upon request from the program staff listed under INQUIRIES.

Applications must be received by October 20, 1994. If an application is received after that date, it will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the DRG for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the program requirements and criteria stated in the RFA is an NIDCD staff function. If the application is not responsive, it will be returned to the applicant. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDCD. If the number of applications is large compared to the number of awards to be made, a preliminary scientific peer review may be conducted and applications withdrawn from further competition if deemed not competitive for the award. The NIDCD will notify the applicant and institutional official of this action.

Those applications judged to be competitive will be further reviewed for scientific and technical merit in accordance with NIH peer review procedures by an initial review group specifically convened by the NIDCD for this RFA. A site visit or applicant interview in Bethesda, Maryland will be considered, if appropriate. The site visit team and/or IRG may recommend adjustments, as judged appropriate, in the requested budgets and periods of support for the components of the program which are deemed to be of significant and substantial merit. Following the review, the applications will be given a second level of review by the Advisory Council unless not recommended for further consideration by the initial review group.

Complete review criteria are described in the RFA.

AWARD CRITERIA

Funding decisions will be based on priority score, availability of funds, and programmatic priorities.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Ralph F. Naunton, M.D.
Division of Communication Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Executive Plaza South, Room 400-C
6120 Executive Boulevard
Rockville, MD 20892
Telephone: (301) 496-1804
FAX: (301) 402-6251

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.3 . Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL RESEARCH SERVICE AWARDS FOR INDIVIDUAL POSTDOCTORAL FELLOWS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

PA NUMBER: PA-94-055

P.T.

National Institutes of Health

Application Receipt Dates: August 5, December 5, and April 5

PURPOSE

Introduction

This is an updated and expanded program announcement for the National Institutes of Health (NIH), National Research Service Award, Individual Postdoctoral Fellowship. It applies to all NIH funding Institutes and Centers, including the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health. A complete list of NIH institutes and centers (hereafter referred to as Institutes) can be found under INQUIRIES.

The main changes in this program announcement are the new application receipt and review dates, effective April 1, 1993, the revised payback provisions, effective June 10, 1993, and the revised stipend levels, effective with Fiscal Year 1994 awards.

The Congress of the United States established the National Research Service Award (NRSA) Program in 1974 to help ensure that highly trained scientists are available in adequate numbers and in appropriate research areas to carry out the Nation's biomedical and behavioral research agenda. Under this congressional authority, NIH awards NRSA individual postdoctoral fellowships (F32s) to qualified applicants, selected as a result of a national competition, to support full-time research training related to the missions of its constituent Institutes.

- o The criteria for evaluating applications focus on the candidate, the research training project, and the training resources and environment, including the sponsor.
- o Awards provide a stipend plus a small allowance to defray some training expenses.
- o The initial 12 months of NRSA postdoctoral support carries a service payback requirement, which can be fulfilled by continued training under the award or by engaging in other health-related research training, health-related research, or health-related teaching.

ELIGIBILITY REQUIREMENTS

Citizenship. At time of application, individuals must be citizens or noncitizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence (i.e., in possession of a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Noncitizen nationals are generally persons born in outlying possessions of the United States (i.e., American Samoa and Swains Island). Individuals on temporary or student visas are not eligible.

Degree Requirements. As of the activation date of the NRSA award, individuals must have received a Ph.D., M.D., D.O., D.D.S., D.V.M., O.D., D.P.M., Sc.D., Eng.D., Dr.P.H., D.N.S., Pharm.D., D.S.W., Psy.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification by an authorized official of the degree-granting institution that all degree requirements have been met is also acceptable.

Sponsorship. Before submitting a fellowship application, the applicant must arrange for appointment to an appropriate institution and acceptance by a sponsor who will supervise the training and research experience. The institution may be private (nonprofit or for-profit) or public, including a Federal laboratory.

Applicants requesting foreign training must show in the application that the foreign institution and sponsor offer special opportunities that are not currently available in the United States. Only in cases where there are clear scientific advantages will foreign training be supported. Applicants proposing training at their doctorate institution or at the institution where they have been training for more than a year must document thoroughly the opportunity for new training experiences that would broaden their scientific background.

The applicant's sponsor should be a competent, active investigator in the area of the proposed research, who will personally supervise the candidate's research. The sponsor must document, in the application, the availability of staff, research support, and facilities to provide a suitable environment for performing high-quality research training.

MECHANISMS OF SUPPORT

Period of Support. Individuals may receive up to three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual fellowship awards. Exceptions

to the three-year limit require a waiver from the NIH. Individuals interested in a waiver should consult with staff of the relevant NIH Institute.

Characteristics of Programs

The proposed NRSA training must encompass biomedical or behavioral research and offer an opportunity for individuals to broaden their scientific background or to extend their potential for research in health-related areas. For those who have attained a health professional degree, the proposed training may be a part of a research degree program.

Individuals are required to pursue their research training on a full-time basis, devoting at least 40 hours per week to the training program. Research clinicians must devote full-time to their proposed research training and must confine clinical duties within their full-time training to those that are part of the research training experience.

The Secretary of the Department of Health and Human Services (DHHS) is required by law, in taking into account the Nation's overall needs for biomedical personnel, to give special consideration to physicians who agree to undertake a minimum of two years of biomedical or behavioral research. The NIH recognizes the critical importance of training clinicians to become researchers and encourages them to apply. Women, minorities, and individuals with disabilities are also encouraged to apply.

An NRSA may not be used to support studies leading to the M.D., D.O., D.D.S., D.V.M., or other similar health-professional degrees. Neither may these awards be used to support the clinical years of residency training.

Payback

The NIH Revitalization Act of 1993 substantially modified the service payback requirements for individuals supported by the NRSA program. For fellowship awards beginning on or after June 10, 1993, only fellows in the first 12 months of postdoctoral NRSA support will incur a service obligation of one month for each month of support. Postdoctoral fellows in the 13th and subsequent months of NRSA support will incur no further obligation, and such support will be considered acceptable postdoctoral payback service. Thus, individuals who begin their initial NRSA postdoctoral fellowship on or after June 10, 1993 and continue under that award for two years would have paid off their first year obligation by the end of the second year.

Postdoctoral fellows accepting an award covering their first 12 months of NRSA postdoctoral support must sign a payback agreement to engage in health-related research training, health-related research, or health-related teaching for a period equal to their initial 12 months of NRSA postdoctoral support.

Those who do not pay back their obligation through continued NRSA training or other full-time health-related research training may satisfy their obligation by serving in a full-time position in which health-related research and/or teaching constitute the primary activity or, if not serving in a full-time position of this kind, engaging in such research or teaching in a position(s) for periods that average more than 20 hours per week of a full work year.

Full-time academic appointments in a biomedical or behavioral field normally meet the payback requirement. Payback service may also be conducted in a governmental, commercial, or other nonacademic environment, and in the United States or in a foreign country. Examples of acceptable payback service include research associateships/assistantships, postdoctoral research fellowships, and college or high school science teachers. Examples of unacceptable payback service include clinical practice and administrative responsibilities not directly related to scientific research.

Payback service positions are arranged by the individual, not by the NIH. The funding NIH Institute will review and approve the activity at the end of the year in which it occurs. Service to satisfy any outstanding obligation must be initiated within two years after termination of NRSA support, and must be performed on a continuous basis. For individuals who fail to fulfill their service obligation, the United States is entitled to recover the total amount of NRSA funds paid to the individual for the obligated period plus interest at a rate determined by the Secretary of the Treasury. Financial payback must be completed within 3 years, beginning on the date the United States becomes entitled to recover such amount.

Under certain conditions, the Secretary of DHHS may extend the period for starting service, permit breaks in service, extend the period of repayment, or otherwise waive, in whole or in part, the payback obligation of an individual. Questions on payback should be directed to the appropriate Institute contact.

Stipends

NRSAs provide stipends to postdoctoral researchers as a subsistence allowance to help defray living expenses during the research training experience. The awards are not provided as a condition of employment with either the Federal Government or the sponsoring institution.

The stipend level for the first year of NRSA support is determined by the number of years of relevant postdoctoral experience at the time the award is issued. Relevant experience may include research experience (including research in industry), teaching, internship, residency, clinical duties, or other time spent in full-time studies in a health-related field beyond that of the qualifying doctoral degree. Current postdoctoral stipends, effective with Fiscal Year 1994 awards, are as follows:

| Full Years of Relevant Experience | Annual Amount |
|-----------------------------------|---------------|
| Less than 1 | \$ 19,608 |
| 1 | 20,700 |
| 2 | 25,600 |
| 3 | 26,900 |
| 4 | 28,200 |
| 5 | 29,500 |
| 6 | 30,800 |
| 7 or more | 32,300 |

The stipend for each subsequent year of NRSA support is the next level in the stipend structure and begins on the anniversary date of the original activation. No departure from the standard stipend schedule may be negotiated between the institution and the fellow.

For fellows sponsored by domestic non-Federal institutions, the stipend will be paid through the sponsoring institution. For fellows sponsored by Federal or foreign institutions, the monthly stipend payment will be direct deposited in the fellow's U.S. bank account or paid directly to the fellow by U.S. Treasury check.

An institution is allowed to provide funds to a fellow in addition to the stipend paid by the NIH. Such additional amounts may be in the form of augmented stipends (supplementation) or compensation for services.

Stipend Supplementation. Supplementation, when provided, must not obligate the fellow in any way. Additionally, no Federal funds may be used for supplementation unless specifically authorized under the terms of both the program from which such supplemental funds are to be received and the program whose funds are to be supplemented. Under no circumstances may Public Health Service (PHS) grant funds be used for supplementation.

Compensation. An institution may provide additional funds to a fellow in the form of compensation (as salary and/or tuition remission) for services, such as teaching or serving as a laboratory assistant. Compensation for services is not considered stipend supplementation. A fellow may receive compensation for services as a research assistant or some other position on a Federal research grant, including a PHS research grant. However, it is expected that compensated services will occur on a limited, part-time basis apart from the normal training activities, which require a minimum of 40 hours per week, and compensation may not be paid from a research grant that supports the same research that is part of the F32 training experience.

Under no circumstances may the conditions of stipend supplementation or the services provided for compensation interfere with, detract from, or prolong the fellow's approved NRSA training program.

Educational Loans or G.I. Bill. An individual may make use of Federal educational loan funds and assistance under the Veterans Readjustment Benefits Act (G.I. Bill). Such funds are not considered supplementation or compensation.

Concurrent Awards. An NRSA may not be held concurrently with another federally sponsored fellowship or similar award that provides a stipend or otherwise duplicates provisions of the NRSA. However, an individual may accept concurrent educational benefits from the Department of Veteran's Affairs (e.g., G.I. Bill) and from Federal loan funds.

Tax Liability

Section 117 of the Internal Revenue Code applies to the tax treatment of all scholarships and fellowships. Under that section, non-degree candidates are required to report, as gross income, all stipends and any monies paid on their behalf for course tuition and fees required for attendance. Degree candidates may exclude from gross income reported for tax purposes any amount used for tuition and related expenses, such as fees, books, supplies, and equipment required for courses of instruction at a qualified educational organization.

The taxability of stipends, however, in no way alters the relationship between NRSA fellows and institutions. NRSA stipends are not considered salaries. NRSA fellows are not considered to be in an employee-employer relationship with the NIH or the institution in which they are pursuing research training.

The interpretation and implementation of the tax laws are the domain of the Internal Revenue Service (IRS) and the courts. The NIH takes no position on what the status may be for a particular taxpayer, and it does not have the authority to dispense tax advice. Individuals should consult their local IRS office about the applicability of the law to their situations and for information on the proper steps to be taken regarding their tax obligations.

The business office of the sponsoring institution is responsible for the annual preparation and issuance of the IRS form 1099 (Statement of Miscellaneous Income) for fellows paid through the institution (fellows training at domestic non-Federal institutions). The NIH will issue the form for all fellows paid directly by them (fellows training at Federal or foreign laboratories).

Other Training Costs

NIH will provide an institutional allowance of \$3,000 per 12-month period to non-Federal, nonprofit sponsoring institutions to help defray such awardee expenses as tuition and fees, self-only health insurance, research supplies, equipment, travel to scientific meetings, and related items. This allowance is intended to cover training-related expenses for the individual awardee. The allowance is not available until the fellow officially activates the award. If an individual fellow is not enrolled or engaged in training for more than 6 months of the award year, only one-half of that year's allowance may be charged to the grant. The Notice of Research Fellowship award will be revised and the balance must be refunded to the NIH.

The NIH will provide up to \$2,000 for fellows sponsored by Federal laboratories or for-profit institutions for the following specified expenses for the fellow: scientific meeting travel expenses, self-only health insurance, tuition and fees, and books. For fellows at for-profit institutions, the \$2,000 will be paid to the institution for disbursement to the fellow. Funds for fellows at Federal laboratories will be disbursed from the NIH awarding Institute.

Additional funds may be requested by the institution if the training of a fellow involves extraordinary costs for (1) travel to field sites remote from the sponsoring institution or (2) accommodations for fellows who are disabled, as defined by the Americans With Disabilities Act. The funds requested for extraordinary cost must be reasonable in relationship to the total dollars awarded under an F32 and must be directly related to the approved research training project. Such additional funds shall be provided only in exceptional circumstances that are fully justified and explained by the institution.

Travel Expenses. Awards for training at a foreign site include a single economy or coach round-trip travel fare. No allowance is provided for dependents. U.S. flag air carriers must be used to the maximum extent possible when commercial air transportation is the means of travel between the United States and a foreign country or between foreign countries.

Funds are not provided to cover the cost of travel between the fellow's place of residence and a domestic training institution. However, in cases of extreme need or hardship, a one-way travel allowance may be authorized by the sponsoring institution. Such travel must be paid from the institutional allowance.

APPLICATION PROCEDURES

Individuals must submit the Application for Public Health Service Individual National Research Service Award (PHS 416-1, rev. 10/91), including with the application at least three letters of reference. If the applicant has been lawfully admitted to the United States for permanent residence, a notarized statement documenting this status must be submitted with the application.

Applicants and sponsoring institutions must comply with policies and procedures governing the protection of human subjects, the humane care and use of live vertebrate animals, and the inclusion of women and minorities in study populations.

Applicants should indicate in Item 3 (Program Announcement or Request for Applications) on the face page of the application the initials of the NIH Institute (e.g., NIA, NIGMS) most appropriate to the research area of the application. The list of Institutes under INQUIRIES at the end of this announcement will be helpful in selecting the appropriate initials. If the application is submitted in response to a published specific Program Announcement (PA) or Request for Applications (RFA) from a particular NIH Institute, the applicant should identify the number of the PA or RFA in Item 3. This information will be used as a guide in the assignment process.

Application kits and the brochure Helpful Hints on Preparing a Fellowship Application to the National Institutes of Health are available by writing the Grants Information Office, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, Maryland 20892, or by calling (301) 594-7248. A self-addressed mailing label will expedite written requests.

Concurrent Applications. An individual may not have more than one competing NRSA individual fellowship application pending concurrently with the NIH or the PHS.

Application Receipt and Review Schedule

F32 applications undergo an expedited review that takes approximately 5 months. The three annual review cycles are as follows:

| | | | |
|--------------------------------|---------|---------|---------|
| Application Receipt Dates: | Aug 5 | Dec 5 | Apr 5 |
| Initial Review Dates: | Oct/Nov | Feb/Mar | Jun/Jul |
| Secondary Review Dates: | Dec/Jan | Apr/May | Aug/Sep |
| Earliest Possible Start Dates: | Jan 1 | May 1 | Sep 1 |

REVIEW CONSIDERATIONS

Applications receive two sequential levels of review. Initial review groups (IRGs), composed primarily of nongovernment scientists selected for their competence in particular scientific areas, evaluate applications for merit. The Scientific Review Administrator (SRA), a designated Federal official, coordinates the review of applications for each IRG.

After the initial review meeting, the SRA prepares a written summary of the review of each application and forwards it to the appropriate NIH Institute. There, a second level of review is provided by a committee of Institute staff members and a funding decision is made.

Review Criteria

The review criteria focus on three main components:

- o the applicant;
- o the research proposed (both its scientific merit and training potential); and
- o the training resources and environment, including the sponsor.

It is important to remember that the F32 program is a training mechanism and not a research mechanism. Major considerations in the review are the applicant's potential for a productive scientific career, the applicant's need for the proposed training, and the degree to which the research training proposal, the sponsor, and the environment will meet the needed training. For more details, see Review Criteria on page 4 of the instructions for application form PHS 416-1.

Notification

Shortly after the initial review meeting, each candidate will be sent a mailer that includes the IRG recommendation, where appropriate the priority score and percentile rank (except in those cases where the Institute does not percentile fellowships), and information regarding the Institute program official. The Institute automatically forwards a copy of the summary statement to the applicant as soon as possible after receipt from the IRG. Following the second-level review, the Institute will notify each applicant of the final disposition of the application. Any questions on initial review recommendations and funding possibilities should be directed to the appropriate Institute program official, not the scientific review administrator of the IRG.

Award Criteria

The staff of the NIH Institutes use the following criteria in making awards: (1) the IRG recommendation of the overall merit of the application; (2) the relevance of the application to the Institute's research priorities and program balance; and (3) the availability of funds.

Activation. An awardee has up to 6 months from the issue date on the award notice to activate the award. Under unusual circumstances, an NIH Institute may grant an extension of the activation period upon receipt of a specific request form the fellow.

Success Rate

In fiscal year 1993, NIH reviewed 2,075 NRSA F32 applications and made 793 awards, for an applicant success rate of 38.2 percent. The average success rate over the last 5 fiscal years was 38.5 percent. (These data, for all years, include the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health.) Because awards are made by individual Institutes, applicant success rates by Institute may vary. The availability of funds for future awards is contingent upon annual appropriations.

AUTHORITY AND REGULATIONS

NRSAs are made under the authority of Section 487 of the Public Health Service Act as amended (42 USC 288), and Title 42 of the Code of Federal Regulations, Part 66. The following Catalog of Federal Domestic Assistance numbers are applicable to these awards: 93.121, 93.172, 93.173, 93.272, 93.278, 93.282, 93.306, 93.361, 93.398, 93.821, 93.837-93.839, 93.846-93.849, 93.853-93.856, 93.859, 93.862-93.867, 93.880, 93.894, and 93.929.

Fellowships must be administered in accordance with the current National Research Service Award Guidelines for Individual Awards and Institutional Grants, the current PHS Grants Policy Statement, and any terms and conditions specified on the award notice. The following policies are noted.

Certification and Reporting Procedures. No application will be accepted without the applicant signing the certification block which indicates, among other things, intent to meet the payback provisions required under law. No funds may be disbursed until the fellow has started training under the award and an Activation Notice (PHS 416-5) has been submitted to NIH, accompanied by a Payback Agreement (PHS 6031) when the award is for the individual's initial 12 months of NRSA postdoctoral support.

When support ends, the fellow must submit a Termination Notice (PHS 416-7) to the NIH, and if the fellow has a payback obligation, he or she must notify the NIH of any change in address and submit Annual Payback Activities Certification forms (PHS 6031-1) until the payback service obligation is satisfied.

Inventions and Publications. Fellowships made primarily for educational purposes are exempted from the PHS invention requirements. F32 awards will not contain any provision giving PHS rights to inventions made by the awardee.

PHS policy is to make available to the public the results and accomplishments of the activities that it funds. Therefore, it is incumbent upon fellows to make results and accomplishments of their F32 activities available to the public. There should be no restrictions on the publication of results in a timely manner.

Except as otherwise provided in the terms and conditions of the award, the recipient is free to arrange for copyright without approval when publications, data, or other copyrightable works are developed in the course of work under a PHS grant-supported project or activity. Any such copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

Nondiscrimination. The NIH research training and career development programs are conducted in compliance with applicable public laws enacted by the Congress since 1964, which provide that no person shall, on the grounds of race, color, national origin, handicap, or age, be excluded from participating in, be denied the benefits of, or be subjected to discrimination under any program or activity (or, on the basis of sex, with respect to any education program or activity) receiving Federal assistance.

This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

INQUIRIES

For additional information contact the appropriate individual listed below.

NATIONAL INSTITUTE ON AGING (NIA)
Dr. Robin Barr (301) 496-9322

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)
Division of Basic Research
Dr. Ernestine Vanderveen (301) 443-1273

Division of Biometry and Epidemiology
Dr. Mary Dufour (301) 443-4897

Division of Clinical and Prevention Research
Ms. Frances Cotter (301) 443-1206

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)
Dr. Milton Hernandez (301) 496-7291

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)
Dr. Richard Lynn (301) 594-9959

NATIONAL CANCER INSTITUTE (NCI)
Dr. John Schneider or Dr. Andrew Vargosko (301) 496-8580

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)
Ms. Hildegard Topper (301) 496-0104

NATIONAL INSTITUTE OF DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)
Dr. Daniel Sklare (301) 496-1804

NATIONAL INSTITUTE OF DENTAL RESEARCH (NIDR)
Dr. Thomas Valega (301) 594-7617

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)
Division of Diabetes, Endocrinology, and Metabolic Diseases
Dr. Ronald Margolis (301) 594-7549

Division of Digestive Diseases and Nutrition
Dr. Judith Podskalny (301) 594-7539

Division of Kidney, Urologic and Hematologic Diseases
Dr. Charles Rodgers (301) 594-7555

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)
Division of Basic Research
Dr. Charles Sharp (301) 443-1887

Division of Clinical Research
Dr. Arthur Horton (301) 443-4060

Division of Epidemiology and Prevention Research
Dr. Mario de la Rosa (301) 443-6543

Medications Development Division
Dr. Heinz Sorer (301) 443-6270

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)
Dr. Michael Galvin, Jr. (919) 541-7825

NATIONAL EYE INSTITUTE (NEI)
Dr. Maria Giovanni (301) 496-0484

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)
Dr. Michael Martin (301) 594-7753

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)
Division of Blood Diseases and Resources
Dr. Fann Harding (301) 496-1817

Division of Heart and Vascular Diseases
Dr. John Fakunding (301) 496-1724

Division of Lung Diseases
Ms. Mary Reilly (301) 594-7466

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)
Division of Clinical and Treatment Research
Dr. Harry Gwirtsman (301) 443-3264

Division of Epidemiology and Services Research
Dr. Kenneth Lutterman (301) 443-3373

Division of Neuroscience and Behavioral Science
Ms. Mary Curvey (301) 443-3107

Office of AIDS
Dr. Leonard Mitnick (301) 443-6100

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)
Mr. Edward Donohue (301) 496-4188

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)
Dr. Teresa Radebaugh (301) 594-7590

NATIONAL CENTER FOR HUMAN GENOME RESEARCH (NCHGR)
Dr. Bettie Graham (301) 496-7531

NATIONAL CENTER FOR RESEARCH RESOURCES (NCRR)
Dr. Cynthia Pond (301) 594-7933

NOTE: The Office of Alternative Medicine at NIH, as announced in the NIH Guide for Grants and Contracts, Volume 23, Number 1, January 7, 1994, will provide funds for approximately six postdoctoral fellowships in fiscal year 1994. The funds will be provided to the appropriate Institute identified above which will award and administer the fellowship. Interested applicants should consult the above program announcement (PA-94-025) and if applicable, indicate the PA number in item 3 on the face page of the application. For further information, contact Dr. John Spencer (301) 402-4333

OTHER PHS ORGANIZATION MAKING F32 AWARDS

AGENCY FOR HEALTH CARE POLICY AND RESEARCH (AHCPR)
Ms. Donna Rae Castillo (301) 594-1362

OTHER SUPPORT

NIH provides other postdoctoral opportunities for training and career development for individuals interested in biomedical and behavioral careers. Among these are:

- o NRSA Institutional Training Grants
- o NRSA Senior Fellowships
- o International Research Fellowships and Minority International Institutional Training Grants (FIC)
- o Medical Informatics Post-Doctoral Fellowships and Fellowships in Applied Informatics (NLM)
- o Minority Access to Research Careers Faculty Fellowships (NIGMS)
- o Minority Faculty Development Awards and Minority NRSA Institutional Training Grants (NHLBI)
- o Career Opportunities in Research Faculty Fellowship Program (NIMH)
- o Research Supplements for Under-represented Minorities
- o Research Supplements to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers
- o Research Supplements to Promote Reentry into Biomedical and Behavioral Research Careers

Individuals interested in the above programs are encouraged to contact the relevant F32 Institute contact listed under INQUIRIES in this announcement. The contact for the Fogarty International Center is Ms. Eileen Trevisan, (301) 496-1653, and the contact for the National Library of Medicine is Dr. Roger Dahlen, (301) 496-4221.

For a complete description of programs that provide scientific training support at levels from high school to the senior investigator level, and for training at research institutions, colleges, and universities around the United States, in other countries, and at the NIH facilities, please refer to Research Training and Career Development Programs Supported by the National Institutes of Health. (NIH Publication No. 92-2273). This booklet can be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. A self-addressed mailing label will expedite written requests.

COMPREHENSIVE PREVENTION RESEARCH IN DRUG ABUSE

NIH GUIDE, Volume 23, Number 15, April 15, 1994

PA NUMBER: PA-94-056

P.T.

National Institute on Drug Abuse

PURPOSE

The purpose of this program announcement is to encourage rigorous scientific study of the efficacy and effectiveness of multiple component substance abuse prevention technologies implemented across several systems including schools, families, peers, and the social environment (workplace and community) to determine their efficacy and effectiveness in preventing the onset of drug use and progression to abuse. Research focused on the prevention of drug use and the prevention of drug abuse is encouraged. Studies should involve the use of randomized controlled clinical trials or well-controlled quasi-experimental research designs. A secondary goal of the proposed research is the development of psychometrically-sound measures, instruments and data collection procedures to assess the process, outcome, and impact of comprehensive prevention strategies. Special attention should be given to culturally-diverse populations and to sub-populations at high-risk of drug use onset and progression. Research should focus on a broad spectrum of drug behaviors, such as the use of tobacco products, marijuana, cocaine/crack, IV drug use, prescription/over-the-counter medications, and polydrug use/abuse. Research is encouraged that focuses on rural and inner-city populations. Finally, health services research that assesses the effectiveness of comprehensive drug preventive care service systems in real world settings is also requested under this program announcement.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Comprehensive Prevention Research in Drug Abuse, is related to the priority area of alcohol and other drug abuse. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applicants from minority individuals and women are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) Awards.

MECHANISM OF SUPPORT

Support mechanisms include research project grants (R01), small grants (R03), FIRST awards (R29), program projects (P01), and Investigator-initiated Interactive Research Project (IRPG) grants (NIH PA number PA-93-078). Because the nature and scope of the research proposed in response to this program announcement may vary, it is anticipated that the size of an award will also vary.

RESEARCH OBJECTIVES

Background

Epidemiologic research over the last fifteen years indicates that significant changes in the use of marijuana and cocaine are related to shifts in the perception of the harmful consequences of drug use and abuse and personal and social disapproval of the use of illicit substances. Controlled intervention research indicates that comprehensive drug prevention programs can promote the formulation of anti-drug social norms and thereby prevent the incidence and reduce the prevalence of the use of cigarettes, alcohol, marijuana, and cocaine for adolescents exposed to comprehensive prevention programs in comparison to those youth not receiving these interventions.

Such programs include systematic implementation of multiple components such as effective use of the media; drug education and intervention in the schools and workplace; parent education especially during prenatal, infancy, toddler stage, and early adolescence; formation of self-help groups; development of community coalitions to combat drug abuse and drug distribution; and, enactment and enforcement of salient anti-drug policies within schools, the workplace, and communities.

The specific objectives of this research program are to determine the efficacy and effectiveness of comprehensive drug prevention programs in two general areas: (1) to measure the short- and long-term effects of comprehensive drug prevention, and (2) to assess the generalizability of these research findings to high-risk populations.

Areas of special interest to this program announcement include, but are not limited to:

Strengthening the Development of Positive Self-Regulated Health Behaviors

Research is needed to apply our knowledge of relevant determinants of drug use to the design and testing of interventions that strengthen the development of positive self-regulated health behaviors. Etiologic research indicates that drug use and abuse involves a number of risk factors relevant to the individual, family, peer group, and social environment and represents only one of a constellation of interrelated problem behaviors to include: delinquency, academic failure and dropping out of school, juvenile depression, running away from home, unwanted pregnancies, suicidal behavior, sexually transmitted diseases to include HIV infection, and drug/alcohol related traffic accidents. Current prevention intervention research suggests that a comprehensive approach to drug abuse prevention offers the best chance of positively effecting this complex problem. The premise of comprehensive drug prevention is that program activities should focus on the individual and his or her interactions with the social environment.

Relevant to the individual, research indicates that a promising approach to prevention would be one that promoted self-regulated health behavior. Research is needed to test the effects of preventive strategies for developing and maintaining: (1) behavior skills, such as self-monitoring, goal setting, self-incentives; (2) cognitive structures, such as self-efficacy and intrinsic motivation; (3) perceptions of the harmful consequences of drug use/abuse; (4) awareness of personal and social disapproval of drug use/abuse; and (5) affective/emotive impulse controls. Research is needed to assess how planned interventions focused on these outcomes can strengthen self-regulated health behavior changes and potentially reduce drug use/abuse. However, research indicates that focusing only upon the individual is insufficient given the vital role played by family, neighbors, peers, friends, teachers, and others in the social environment to encourage and reinforce positive health behavior changes, specifically in regard to the onset, use, and abuse of cigarettes, alcohol, marijuana, crack/cocaine and other drugs. Research is needed to assess how social environments can be structured and strengthened to promote positive self-regulated health behavior change.

Multiple Component and Comprehensive Prevention Interventions

Research is needed to assess multiple component and comprehensive strategies that simultaneously utilize the schools, media, family, peers, social networks, and health policies to both shape and reinforce the process of self-regulated health behavior change. Intervention research indicates that a comprehensive approach to drug abuse prevention that includes multiple program components can prevent the use of cigarettes, alcohol, marijuana, and cocaine by youth exposed to the program in comparison to controls. Research is needed to test a variety of multiple component prevention strategies. For example, the combination of drug prevention media and school/home-based prevention education premised upon social learning theory may equip youth with generalizable assertiveness skills needed to resist peer pressure to use drugs. Research on the use of mass media combined with school-based prevention education programs has been encouraging and indicates that these two components are essential elements of comprehensive drug prevention programming. Media can increase public awareness of drug abuse problems, promote organizational involvement in preventing substance abuse, create public agendas for community action, strengthen drug-free social norms, stimulate interpersonal discussions relevant to prevention of drug problems, and reinforce changes in relevant health behaviors of individuals residing within the community. School and home-based social skills training can provide individuals with the specific behavioral competency to resist and resolve the inter- and intra-personal pressures to use drugs and alcohol. Research suggests that parent education and life skills training can increase family communication, enhance the use of positive family management techniques, and promote social bonding within the family. Research is needed to assess the efficacy of comprehensive drug prevention that includes parent education. In addition, research is needed to assess comprehensive drug prevention that includes components focused upon re-structuring the social influences of the peer group, increasing the social bonding of youth to school, home, workplace, church or neighborhood youth group, and exposure to positive role models provided by caring adult neighborhood volunteers, such as mentoring. Research is needed for a variety of prevention strategies to include: family preservation models, student assistance programs, modification of school environments, and in-home interventions.

Community Organization, Empowerment, and Change

Research indicates that to be effective, comprehensive drug prevention needs to extend beyond the individual and social networks represented by interactions with family, peers, and significant others in the neighborhood, and include salient changes in community values, norms, sanctions, and actions relevant to preventing drug use/abuse and neighborhood drug distribution activities. Research is needed to design and test drug prevention strategies that involve community organizations and institutions that establish an environment in which durable, positive self-regulated health behavior change can be developed and maintained. Community involvement and commitment to substance abuse prevention has been traditionally a desired goal of public health programs. However, much is yet to be learned concerning the validity of

prevention theories prescriptive of community organization and empowerment and the efficacy of community change interventions based upon these theories. Research is needed to develop and test models of community/environmental change that capitalize upon existing community leadership and organizations to deliver effective drug education messages, encourage environmental change, promote drug-free norms, and establish community coalitions to take effective preventive/deterrent actions particularly within high risk neighborhoods. Research is needed to develop and test the most effective techniques for community change that may involve community advisory boards, task forces, parent groups, professional associations, individual community leaders and relevant grass roots entities. Innovative techniques need to be created and assessed to expand and intensify participation in drug prevention by a variety of community groups representing ethnic-minority points of view. Research is needed to assess the efficacy of grass-roots community coalitions that have been formed to rid their neighborhoods of open-air drug markets and crack houses. Prevention research is needed to assess the short-term and long-term effects of community-based drug abuse deterrence on both drug use/abuse and the drug distribution marketplace and the violence that relates to the presence of drugs in communities.

Research is needed to assess the efficacy of drug-related policies and legislation to establish drug-free school and community zones and a drug-free workplace. Research indicates that effective enforcement of drug-free policies and legislation can reduce consumption of drugs to include the use of tobacco products in schools, communities, and the workplace and drug use/abuse in the military. Research is needed to determine how drug-free policies and legislation can enhance the effects of more traditional comprehensive drug prevention activities involving schools and families.

Health Services Research

The intent of health services prevention research is to assess the effectiveness and cost effectiveness of preventive interventions in reducing drug-related problems, such as adverse medical, psychological, or social consequences of drug use. In addition to intervention studies in health care settings, prevention services research may occur in a variety of other settings (e.g., worksites, schools, and local communities) and may focus on financing, organization, management, enforcement, and utilization of prevention services as well as their effectiveness.

Research is needed to improve the quality of prevention services, to expand access to prevention services to all populations, particularly minorities, and to lower costs of health care by reducing the extent of drug use and its adverse health and social consequences.

Illustrative drug abuse prevention services research areas include:

- o Qualitative and quantitative assessment of program service delivery at the community, state, regional, or national level;
- o Outreach research to assess strategies to expand prevention services to under-served populations and geographic areas, such as rural communities and inner cities; and,
- o Research to integrate drug prevention with other related behavioral and societal disorders such as violence prevention, unwed pregnancy, school drop-outs, and domestic abuse.

Prevention Interventions In Rural Communities

Research suggests that drug abuse in rural communities is on the increase and requires special attention through the design and testing of prevention programs and policies that best serve the needs of rural America. Prevention intervention research focused upon rural communities is encouraged by this program announcement

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines indicated in the application kit. Receipt dates for applications for AIDS-related research are found in the PHS 398 instructions. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248). The title and number of this program announcement must be typed in Item 2a on the face page of the application.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by review groups in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level of review by the appropriate national advisory council. Small grant (R03) applications do not receive a second-level of review.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the NIDA. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review, program priorities, and availability of funds.

INQUIRIES

Written and telephone inquiries to clarify any issues or questions from potential applicants are encouraged.

Direct inquiries regarding programmatic areas to:

William J. Bukoski, Ph.D.
Division of Epidemiology and Prevention Research
National Institute on Drug Abuse
5600 Fishers Lane
Parklawn Building, Suite 9A53
Rockville, MD 20857
Telephone: (301) 443-1514

Direct inquiries regarding fiscal or grant management issues to:

Gary Fleming, J.D., M.A.
Grants Management Branch
National Institute on Drug Abuse
Parklawn Building, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of Public Health Service Act, Sections 301 (42 USC 241) and administered under PHS grants policies and Federal Regulations at Title 42 CFR Part 52, "Grants for Research Projects," Title 45 CFR parts 74 & 92, "Administration of Grants," and 45 CFR Part 46, "Protection of Human Subjects." Title 42 CFR Part 2 "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Sections of the Code of Federal Regulations are available in booklet form from the U.S. Government Printing Office. Awards must be administered in accordance with the PHS Grants Policy Statement (rev. 10/90), which may be available from your office of sponsored research.

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

PHYSIOLOGY AND PATHOLOGY OF LOW CHOLESTEROL STATES

NIH GUIDE, Volume 23, Number 15, April 15, 1994

PA NUMBER: PA-94-057

P.T.

National Heart, Lung and Blood Institute
National Institute on Aging

PURPOSE

The purpose of this program announcement is to foster research that will improve the understanding of low cholesterol states in health and sickness. Applications are sought for basic and applied research drawing from the disciplines of biochemistry, physiology, pathology, genetics, nutrition, clinical medical sciences, and psychosocial (behavioral) sciences.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Physiology and Pathology of Low Cholesterol States, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

MECHANISM OF SUPPORT

This program seeks applications for research project grants (R01) and FIRST awards (R29). Because the nature and scope of the research proposed in response to this PA may vary, it is anticipated that the size of awards will vary as well.

RESEARCH OBJECTIVES

Background

Interest in low cholesterol states has increased in recent years. The final report of the 1990 NHLBI workshop on Low Cholesterol: Mortality Associations (Circulation 1992; 86:1046-1060) described how a large number of observational epidemiological studies show a consistent J-shaped curve relationship between total cholesterol level and total mortality risk, with increased mortality rates observed in males having very low cholesterol levels (120-140 mg/dL and below). The interpretation of the J-shaped curve was difficult, however, because observational studies do not collect the type of data needed to clarify the biological basis of this phenomenon. Similarly, the degree to which the curve reflects underlying confounding could not be determined.

The J-shaped curve observation has been used to buttress arguments that there are risks of noncardiovascular illness and death associated with the cholesterol-lowering approaches advocated for the prevention of cardiovascular disease in populations. This school of thought, particularly prevalent in Europe and the United Kingdom, but also advocated in the United States, extrapolates that phenomena responsible for the U-shaped curve also apply to the upper half of the plasma cholesterol distribution, where cholesterol-lowering efforts are directed. Given the great effort that has been put towards research and public education programs regarding the expected benefits of cholesterol lowering, this issue must be considered seriously.

It has been difficult to reconcile the concerns expressed about cholesterol lowering with most of the other data on low cholesterol conditions. Healthy animals eating diets in the wild usually have low cholesterol levels. Some of the human populations living under circumstances of adequate sanitation (in Japan, for example) are known to consume relatively low fat, low cholesterol diets compatible with both low blood cholesterol levels and generally good health. Some individuals simply maintain low cholesterol levels despite eating a high fat diet. Individuals with hypobetalipoproteinemia usually appear to enjoy good health and some markedly long-lived kindreds have been described. At the same time, it is clear that a low cholesterol level can be caused not only by certain genetic conditions, but also can be an epiphenomenon of conditions such as weight loss, infection, hyperthyroidism, liver disease, anemia, malabsorption and certain types of cancer. In geriatric patients with severe weight loss and markedly elevated mortality risk, it is unclear whether the hypocholesterolemia that often accompanies this reflects an underlying pathophysiologic cause or is an epiphenomenon. What makes the hypocholesterolemia of good health different from that of illness?

Proposed Research

This program announcement seeks to elicit a diverse group of applications to explore the biology and pathophysiology of low cholesterol conditions. A consortium arrangement may be necessary to support inter-institutional research collaboration. Well-designed studies proposing hypothesis-testing research in humans and animals are preferred.

Potential areas for investigation could include, but are not limited to, the following:

- o Studies of hypobetalipoproteinemic kindreds and individuals, including genetic, metabolic, clinical and psychosocial studies.
- o Studies of other low cholesterol states, including low cholesterol associated with various co-morbid conditions, and the mechanisms whereby they arise.
- o Studies in transgenic animal models, especially those that preserve a low plasma cholesterol level when fed diets that usually are hypercholesterolemic.
- o Studies, particularly in humans, of the mechanisms underlying of the hyporesponse to high fat, high cholesterol diets.
- o Studies yielding reliable estimates of the frequency of hypocholesterolemia due to various causes.
- o Studies on causes and pathophysiologic significance of hypocholesterolemia in geriatric patients with severe weight loss, including its relationship to nutritional and other metabolic factors.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The title and number of this program announcement must be typed in Section 2a on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures.

Following scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other applications assigned to that ICD. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Abby G. Ershow
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 401
Bethesda, MD 20892
Telephone: (301) 496-1681
FAX: (301) 496-9882

Dr. Pamela E. Starke-Reed
Office of Nutrition
National Institute of Aging
Gateway Building, Suite 2C231
Bethesda, MD 20892
Telephone: (301) 496-6402
FAX: (301) 402-0010

Direct inquiries regarding fiscal matters to:

Mr. William Darby
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 594-7458
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.837. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RESEARCH TRAINING: ENVIRONMENTAL HEALTH AND NURSING SCIENCES

NIH GUIDE, Volume 23, Number 15, April 15, 1994

PA NUMBER: PA-94-058

P.T.

National Institute of Environmental Health Sciences
National Institute of Nursing Research

Application Receipt Dates: May 10 (T32); and August 5, December 5, and April 5 (F31, F32)

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) and the National Institute of Nursing Research (NINR) announce their interest in receiving individual and institutional National Research Service Award (NRSA) applications for support of training at the pre- and postdoctoral level of nurses interested in pursuing research careers combining environmental health and nursing sciences. The purpose is to provide a cadre of nurse investigators who are prepared to apply the principles of clinical nursing research to environmental health research problems.

This program announcement (PA) on Research Training in Environmental Health and Nursing Sciences is an abbreviation of larger, NIH-wide program announcements on Individual and Institutional NRSA programs. Copies of the relevant program announcement may be requested from the NIH Office of Grants Information at (301) 594-7248.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Research Training in Environmental Health and Nursing Sciences, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications for T32 support may be submitted only by domestic, non-profit, private and public institutions. The applicant institution must have the staff and facilities required for the proposed program. The training program director at the institution will be responsible for the selection and appointment of trainees to receive NRSA support and for the overall direction of the program. Applications from minority individuals and women are encouraged.

In order to facilitate the growth of scientists in this developing area, the NIEHS has determined that this research training could be facilitated as a part of an ongoing research training program. Therefore, competitive supplements to existing NIEHS training programs are strongly encouraged. The availability of these supplements does not apply to NINR supported training programs.

Applications for F32 support may be submitted only by citizens or noncitizen nationals of the United States or by individuals who have been lawfully admitted to the United States for permanent residence. Additionally, applicants for postdoctoral study must have received a doctorate prior to the beginning date of the proposed fellowship. Thus, at the time of activation of the NRSA award, an individual must have received a Ph.D., Sc.D., D.W.S., or other equivalent doctoral degree.

Applicants for F31 support must be registered nurses with an active license and either a baccalaureate or master's degree in nursing. Applicants must be United States citizens or have been lawfully admitted to the United States for permanent residence and have in their possession a permanent visa at the time of application. Prior to formal submission of the NRSA application, an applicant must have been admitted to a doctoral program of study and accepted by a faculty sponsor who will supervise the applicant's training and research experience.

MECHANISM OF SUPPORT

The mechanisms of support are the Individual and Institutional National Research Service Awards (F31, F32, T32). Applications for the F31 will be considered only by the NINR. Individuals may receive up to three years of aggregate NRSA support at the postdoctoral level, and up to five years of support at the predoctoral level. Institutional applicants (T32) may request up to five years of support. As indicated above, competitive supplements to existing NIEHS T32s are strongly encouraged. These supplements are not available to NINR supported training programs. The stipend level for the first year of postdoctoral NRSA support is determined by the number of years of relevant postdoctoral experience at the time the trainee is appointed. The stipend levels for predoctoral and postdoctoral trainees is established in an NIH-wide announcement. See NIH Guide Vol 23, No. 10, March 11, 1994.

Supplementation to stipends, when provided, must not require obligation from the fellow. Under no circumstances may Federal grant funds be used for supplementation unless specifically authorized under the terms of the program from which the funds are derived.

RESEARCH OBJECTIVES

The traditional focus of research supported by the NIEHS has been to identify those factors in the environment that have adverse health effects on humans, the nature of those effects, and the mechanisms responsible for them. Over the past few years, the translation of the information derived from this research into clinical research and practice and public health has emerged as a high priority of the NIEHS. In order to accomplish this, there must be a cadre of appropriately trained health care providers and public health practitioners.

In 1990, the NIEHS initiated a program in Environmental and Occupational Medicine (EOM), which is targeted to the training of medical students in EOM. The initiative is expected to have a long-term impact on the extent to which environmental factors are recognized as determinants in disease and dysfunction. It is clear that nurse scientists could actively contribute to expanding our understanding of these linkages, and thus are important targets for translation activities. Numbering approximately two million nationwide, registered nurses represent the largest group of health care providers, and are often the initial, perhaps only, point of contact for individuals seeking health care for illnesses that may result from environmental exposures. Thus, they may play a strategic role in both the identification of environmentally-related illnesses and the implementation of prevention/intervention strategies.

As research institutes, the primary focus of training activities of both the NIEHS and the NINR relates to addressing the need to develop qualified nurse scientists and to seed a new scientific specialty. Given the current visibility and high level of interest in environmental health and its relationship to the health of the public, an opportunity exists to begin building the linkages between environmental health and nursing science.

This program is focused on developing a cadre of nurse scientists who are trained in environmental health research. The specific research training mix and expertise to be provided is the responsibility of the institution; however, it is likely that some of the characteristics of such programs would include the following:

- a. Applicants for T32s should be either: (1) Schools of Nursing with formal links to Environmental Health Science Programs such as those at Schools of Public Health or other graduate schools or, (2) Environmental Health Sciences Programs with formal linkages to Schools of Nursing.
- b. Applicants for T32s should have existing doctoral programs both in nursing and in environmental health sciences.
- c. Goal of the research training program should be to prepare nurses for a research career in environmental health and nursing sciences.
- d. Applicants for F32s must present a program of research training that includes both environmental health and nursing science.
- e. Applicants for F31s must be enrolled in doctoral programs in either nursing or environmental health sciences which have the appropriate linkages.

APPLICATION PROCEDURES

Applications for institutional training grants (T32) will be accepted in accordance with the usual receipt date of May 10; and for individual fellowships (F31, F32) on April 5, August 5, and December 5. The earliest possible award date for an Institutional Training Grant or supplement will be July 1 of the following year. For fellowships, the award date will be approximately six months after the respective receipt dates. F31 and F32 applications received too late for one cycle of review will be held until the next receipt date.

Applications will be received by the NIH Division of Research Grants (DRG) and referred, according to standard PHS procedures, to an initial review group for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines.

In general, the NIEHS has the responsibility for the support of research and research training related to the effects of the environment on human health. The NINR is responsible for support of research and research training related to promoting health, preventing disease, ameliorating the effects of illness and disability, strengthening the environments in which health care is provided, and improving systems of health care delivery.

Applications for T32 awards are to be submitted on form PHS 398 (rev. 9/91) and applications for F31, F32 awards are to be submitted on form PHS 416-1 (rev. 10/91). These forms are available in the office of sponsored research at most academic and research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248 (one copy) or (301) 594-7378 (multiple copies).

To identify the application as a response to this program announcement, check "YES" in Item 2a on the face page of the application and enter the program announcement title, "Research Training in Environmental Health and Nursing Sciences", and program announcement identification number.

The original and five copies of the PHS 398 application form or two copies of the PHS 416-1 must be sent or delivered to:

Applications Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The review criteria customarily employed by the NIH will prevail. Following the initial scientific review, the applications will be evaluated either by the National Advisory Council for the assigned institute for T32 applications or an institute committee for F31 and F32 applications.

AWARD CRITERIA

Applications will compete for available funds with all other approved NRSA applications assigned to that Institute. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review.
- o Availability of funds.
- o Program balance among training areas.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issue or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Dr. Michael Galvin, Jr.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-02
Research Triangle Park, NC 27709
Telephone: (919) 541-7825
FAX: (919) 541-2843

Dr. Judith Laughlin
Nursing Systems Branch
National Institute of Nursing Research
Westwood Building, Room 738
Bethesda, MD 20892
Telephone: (301) 594-7493
FAX: (301) 594-7603

Grants management inquiries may be directed to:

Ms. Jacqueline M. Russell
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, Building 2
Research Triangle Park, NC 27709
Telephone: (919) 541-7628
FAX: (919) 541-2860

Ms. Sally A. Nichols
Grants Management Office
National Institute of Nursing Research
Westwood Building, Room 748
Bethesda, MD 20892
Telephone: (301) 594-7498
FAX: (301) 594-7603

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.894, Resource and Manpower Development in the Environmental Health Sciences; 93.361, Nursing Research. Awards are made under the authority of Section 487, Public Health Service Act as amended (42 USC 288) and administered under PHS Grant Policies and Title 42 of the Code of Federal Regulations, Part 66; and the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Health Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATA

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR THE TREATMENT OF OPPORTUNISTIC INFECTIONS AND TUBERCULOSIS IN AIDS

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA: AI-94-014

P.T.

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: July 15, 1994

Application Receipt Date: August 11, 1994

The Request for Applications (RFA) AI-94-014, published in the NIH Guide for Grants and Contracts, Vol. 23, No. 12, March 25, 1994, contained an incorrect title for the Notice of Availability and the RFA. The correct title is NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR THE TREATMENT OF OPPORTUNISTIC INFECTIONS AND TUBERCULOSIS IN AIDS. The dates for receipt of letters of intent and applications are unchanged.

CLONING AND SEQUENCING THE BRCA1 GENE

NIH GUIDE, Volume 23, Number 15, April 15, 1994

RFA: CA-94-021

P.T.

National Cancer Institute

Application Receipt Date: June 14, 1994

The following correction is issued for RFA CA-94-021, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 14, April 8, 1994.

The fourth paragraph under APPLICATION PROCEDURES is amended to read as follows:

At the time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Referral Officer
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636
6130 Executive Boulevard
Rockville, MD 20852 (if hand-delivered or delivery service)

Bethesda, MD 20892 (if using the U.S. Postal Service)

It is important to send these copies at the same time that the original and three copies are sent to DRG; otherwise, the NCI cannot guarantee that the applications will be reviewed in competition with other applications received on or before the designated receipt date.

****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue
Bethesda, MD 20816

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NIH GUIDE

For Grants and Contracts

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Printing & Reproduction Branch
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Building 31, Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 16
April 29, 1994

RICHARD W HURRY

* 340189
S1350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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NOTICES

NATIONAL ANIMAL WELFARE EDUCATION WORKSHOP

NIH GUIDE, Volume 23, Number 16, April 29, 1994

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, Office for Protection from Research Risks is continuing to sponsor workshops on implementing the Public Health Service Policy on Humane Care and Use of Laboratory Animals. Each of the workshops scheduled for Fiscal Year 1994 will focus on a specific theme.

The workshops are open to institutional administrators, members of Institutional Animal Care and Use Committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs. Ample opportunities will be provided to exchange ideas and interests through question and answer sessions and informal discussions.

MIDWEST REGION

DATES: MAY 5-6, 1994

TOPIC: Training and Education: Institutional Improvement - Crisis Prevention

LOCATION

Stewart Center and Memorial Union, Campus of Purdue University

SPONSOR

Purdue University

REGISTRATION

Ms. Lisa D. Snider, Administrative Assistant
Laboratory Animal Program
Purdue University
1071 South Campus Courts-D
West Lafayette, IN 47907-1071
Telephone: (317) 494-7206
FAX: (317) 494-0793

FEE: \$150.00 - Regular; \$50.00 - Graduate Students/Post-Docs

DESCRIPTION: The general theme will focus on continuing education and training as mandated by the National Institutes of Health and USDA. The format will include panel discussions and concurrent breakout sessions. The group discussions will address occupational health; analgesia/pain/surgery; euthanasia; and tailoring the CET programs to specific audiences.

NORTHWEST REGION

DATES: AUGUST 4-5, 1994

TOPIC: Sharing Animal Welfare Responsibilities Between Affiliated Institutions

LOCATION

Portland Marriott Hotel, Portland, OR

SPONSOR

Department of Veterans Affairs

REGISTRATION

Ms. Margaret Doherty
Veterans Affairs Medical Center
P.O. Box 1034
Portland, OR 97207-1034
Telephone: (503) 220-8262 Ext. 7610
FAX: (503) 273-5351

FEE: \$150 - Regular; \$100 - Students and Technicians

DESCRIPTION: The workshop will explore the relationships among academia, government, and industry as they pertain to the care and use of laboratory animals and animal research facilities and programs. The speakers will focus on issues such as sorting out collaborations, assuming responsibility; VA vs Academia; cost and benefits of industrial contracts and agreements; building a shared institutional animal care and use committee; and the regulatory agencies' perspective and oversight.

SOUTHEASTERN REGION

DATES: September 29-30, 1994

TOPIC: Use of Animals in Research and Alternatives

LOCATION

Monteleone Hotel, New Orleans, LA

SPONSORS

Louisiana State University Medical Center
Xavier University of Louisiana

REGISTRATION

Ms. Lois Herbez, Administrative Secretary
Louisiana State University Medical Center
1542 Tulane Avenue
New Orleans, LA 70112
Telephone: (504) 568-4198
FAX: (504) 568-4843

FEE: \$150

DESCRIPTION: The theme of the workshop will address various aspects of the use of animals in research and the role of animals and alternatives in research and education. The workshop will address such issues as (1) Adequacy of Computer Searches; (2) NIH, USDA, FDA Alternatives Initiative; (3) Occupational Health - Implementation, Update and Biosafety Concerns; (4) Roles of Animals and Alternatives in Education.

INQUIRIES

For further information concerning these workshops and future NIH Animal Welfare Education Workshops, contact:

Ms. Roberta Sonneborn
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B63
Bethesda, MD 20892
Telephone: (301) 496-7163
FAX: (301) 402-2803

NIH REGIONAL SEMINAR -- SPECIAL TOPICS

NIH GUIDE, Volume 23, Number 16, April 29, 1994

P.T. 34; K.W. 1014006

National Institutes of Health

The National Institutes of Health (NIH) is sponsoring an NIH Regional Seminar on Special Topics on May 18-19, 1994, at the Condado Plaza Hotel in San Juan, Puerto Rico. See the NIH Guide for Grants and Contracts, Vol. 23, No. 10, March 11, 1994 for details. Advance seminar registration is required by May 2, 1994.

INQUIRIES

For registration materials, send a FAX that provides your name, institution, address, telephone number, and anticipated number of registrants to:

Mr. Frederick B. Mesler
Telephone: (409) 845-8629
FAX: (409) 845-7143

CLINICAL COORDINATING CENTER FOR THE ANGIOGRAPHIC TRIAL IN WOMEN

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFP AVAILABLE: NHLBI-HV-94-16

P.T. 34; K.W. 0755015, 0755018, 0715040

National Heart, Lung, and Blood Institute

The Lipid Metabolism-Atherogenesis Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) has a requirement for the establishment of a clinical coordinating center to access whether hormonal replacement therapy and/or antioxidant treatment will stabilize or inhibit progression and induce regression of coronary plaques in women. In addition, the mechanisms by which these treatments may modify atherosclerosis in women will be explored. Angiographic changes will be primary endpoints of this trial. Other endpoints, such as carotid and intracoronary ultrasound, magnetic resonance coronary angiography, assessment of endothelial function, may be proposed and will be considered during protocol development. Quantitative computerized analysis of the angiograms will be performed by a central laboratory. In addition, it is proposed to follow lipid and clotting parameters that will be analyzed by a central laboratory facility.

The study population will consist of 450 postmenopausal women with angiographically documented CAD defined as at least 30 percent but no more than 75 percent occlusion of any single coronary artery. In order to assure that the study will provide meaningful data on diverse racial/ethnic groups, the overall goal will be to recruit 50 percent minority women. The following will be exclusion criteria: (1) age over 75; (2) any condition that would compromise participation in the study or the likelihood of obtaining exit angiograms, such as a life-threatening disease or a chronic illness likely to require frequent hospitalizations and/or treatment adjustments that may affect outcome variables; (3) contraindications to the use of any of the study interventions; and (4) clear need for treatment with any of the interventions for this trial. It is estimated that 50 percent of eligible women requiring angiographic evaluation will agree to participate in the study, and 50 percent of these women will meet the angiographic criteria. The study will have a 2x2 factorial design and roughly equal numbers of eligible women will be randomized into four treatment groups: (1) both active therapies (hormone replacement and antioxidant), (2) active hormone replacement therapy and antioxidant placebo, (3) active antioxidant therapy and hormone replacement placebo, and (4) double placebo plus usual care. It is expected that hormone replacement therapy will consist of estrogen plus a progestin for most or all gynecologically intact women, and unopposed estrogen for women with hysterectomies. With regards to antioxidants, most likely a combination of vitamin E, beta-carotene, and vitamin C will be used. Allowing for 20 percent attrition over three years of follow-up, it is anticipated that at least 360 women will be analyzed at the end of the study. One award is anticipated. This incrementally funded contract will be awarded for five years. This is not a Request for Proposals (RFP). RFP No. NHLBI-HV-94-16 will be released on or about April 28, 1994.

INQUIRIES

RFP No. NIH-NHLBI-HV-94-16 will be released on or about April 28, 1994. Written requests must include three self-addressed labels and must cite RFP No. NIH-NHLBI-HV-94-16. To insure timely receipt of requests for RFP No. NHLBI-HV-94-16, facsimile requests will be accepted. Requests for copies of the RFP are to be sent to:

Shari L. Spencer
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 4C04
Bethesda, MD 20892
Telephone: (301) 496-6838
FAX: (301) 496-9501

CLINICAL UNITS FOR THE ANGIOGRAPHIC TRIAL IN WOMEN

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFP AVAILABLE: NHLBI-HV-94-17

P.T. 34; K.W. 0755015, 0715040

National Heart, Lung, and Blood Institute

The Lipid Metabolism-Atherogenesis Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI) has a requirement for the establishment of clinical units to assess whether hormonal replacement therapy and/or antioxidant treatment will stabilize or inhibit progression and induce regression of coronary plaques in women. In addition, the mechanisms by which these treatments may modify atherosclerosis in women will be explored. Angiographic changes will be primary endpoints of this trial. Other endpoints, such as carotid and intracoronary ultrasound, magnetic resonance coronary angiography, assessment of endothelial function, may be proposed and will be considered during protocol development. Quantitative computerized analysis of the angiograms will be performed by a central laboratory. In addition, it is proposed to follow lipid and clotting parameters that will be analyzed by a central laboratory facility.

The study population will consist of 450 postmenopausal women with angiographically documented CAD defined as at least 30 percent but no more than 75 percent occlusion of any single coronary artery. In order to assure that the study will provide meaningful data on diverse racial/ethnic groups, the overall goal will be to recruit 50 percent minority women. The following will be exclusion criteria: (1) age over 75; (2) any condition that would compromise participation in the study or the likelihood of obtaining exit angiograms, such as a life-threatening disease or a chronic illness likely

to require frequent hospitalizations and/or treatment adjustments which may affect outcome variables; (3) contraindications to the use of any of the study interventions; and (4) clear need for treatment with any of the interventions for this trial. It is estimated that 50 percent of eligible women requiring angiographic evaluation will agree to participate in the study, and 50 percent of these women will meet the angiographic criteria. The study will have a 2x2 factorial design and roughly equal numbers of eligible women will be randomized into four treatment groups: (1) both active therapies (hormone replacement and antioxidant), (2) active hormone replacement therapy and antioxidant placebo, (3) active antioxidant therapy and hormone replacement placebo, and (4) double placebo plus usual care. It is expected that hormone replacement therapy will consist of estrogen plus a progestin for most or all gynecologically intact women, and unopposed estrogen for women with hysterectomies. With regards to antioxidants, most likely a combination of vitamin E, beta-carotene, and vitamin C will be used. Allowing for 20 percent attrition over three years of follow-up, it is anticipated that at least 360 women will be analyzed at the end of the study. Three to five awards are anticipated. These incrementally funded contracts will be awarded for five years. This is not a Request for Proposals (RFP). RFP No. NHLBI-HV-94-17 will be released on or about April 28, 1994.

INQUIRIES

RFP No. NIH-NHLBI-HV-94-17 will be released on or about April 28, 1994. Written requests must include three self-addressed mailing labels and must cite RFP No. NIH-NHLBI-HV-94-17. To insure timely receipt of requests for RFP No. NHLBI-HV-94-17, facsimile requests will be accepted. Requests for copies of the RFP are to be sent to:

Shari L. Spencer
Contracts Operations Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 4C04
Bethesda, MD 20892
Telephone: (301) 496-6838
FAX: (301) 496-9501

PHASE I STUDIES OF NEW CHEMOPREVENTIVE AGENTS

NIH GUIDE, Volume 23, Number 16, April 29, 1994

MAA AVAILABLE: NCI-CN-45582-41

P.T. 34; K.W. 0715035, 0740018

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Prevention and Control (DCPC), Chemoprevention Branch, in its annual requirement to seek new sources, is soliciting proposals for Master Agreement Holders for the Phase I Studies of New Chemopreventive Agents. The objective of these studies is to determine the parameters and characteristics of toxicity in humans, the safely delivered dose, and the basic clinical pharmacokinetics of agents emerging from the NCI chemoprevention agent program so that subsequent Phase III risk reduction trials can be appropriately designed. The Master Agreement Holder will develop and conduct the following Task I and Task II studies: Task I: Phase I Studies - Phase I studies will provide the parameters and characteristics of drug toxicity, the safely delivered dose and a recommended Phase II/III dose. Phase I clinical studies with combinations of agents may be performed if mutually agreed upon by the Contractor and the Project Officer. TASK II: Pharmacokinetic Studies - Pharmacokinetic studies will provide the parameters of drug absorption, blood concentration--time profiles, distribution and excretion. Using classical and non-classical modeling, the pharmacokinetic data will be used to determine probable patterns of distribution, and excretion, compartmentalization and enterohepatic recirculation, and to include identification as well as distribution and excretion of metabolites. The Master Agreement (MA) shall certify a holder's qualification to compete for both Task I and II. For a given agent tested, qualifications to carry out both Task I and II must exist, although only Task II may be required. A maximum of ten task orders (including both Tasks I and II), requiring approximately 200 subjects, will be issued annually for a period of four years for studies on specific agents.

INQUIRIES

Requests for this solicitation must be in writing and reference Master Agreement Announcement (MAA) No. NCI-CN-45582-41. The MAA will be available approximately May 7, 1994 and due approximately June 27, 1994. Requests are to be addressed to:

Ms. Susan K. Hoffman
Research Contracts Branch
National Cancer Institute
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

EVALUATION OF THE USE OF CLINICAL PRACTICE GUIDELINES

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFA AVAILABLE: HS-94-007

P.T. 34; K.W. 0715123, 0715008, 0715033, 0715072

Agency for Health Care Policy and Research
National Institute of Mental Health

Letter of Intent Receipt Date: June 17, 1994

Application Receipt Date: July 21, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) and the National Institute of Mental Health (NIMH) invite applications for cooperative agreements related to evaluating AHCPR-supported clinical practice guidelines. Specifically, cooperative agreements are sought to evaluate the effects of implementing practice guidelines in primary care. The AHCPR-supported clinical practice guidelines relevant to this RFA are: (1) Urinary Incontinence in Adults; (2) Early HIV Infection: Evaluation and Management; (3) Sickle Cell Disease: Screening, Diagnosis, Management, and Counseling in Newborns and Infants; (4) Unstable Angina: Diagnosis and Management; and (5) Depression in Primary Care: Detection, Diagnosis and Treatment. NIMH will support grants only on the depression guideline.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Evaluation of the Use of Clinical Practice Guidelines, is related to several priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic organizations, public and private, including universities, clinics, State and local governments, and non-profit foundations; or consortium of organizations. The AHCPR by law can support only non-profit organizations or a consortium of organizations, if the application is submitted by a domestic, non-profit, public or private organization. The NIMH can directly support for-profit organizations. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

The administrative and funding instrument for this program will be the cooperative agreement (U01), an "assistance" mechanism in which substantial AHCPR scientific and programmatic involvement with the awardee is anticipated during the performance of the project. The total project period for each application submitted in response to the RFA may not exceed three years. The anticipated award date is September 30, 1994. Award of funding beyond the initial budget period will depend upon annual progress reviews by the AHCPR/NIMH and the availability of funds.

FUNDS AVAILABLE

The AHCPR expects to award a total of \$750,000 for the first year to support up to three awards. NIMH expects to award a total of \$750,000 for the first year to support up to three awards for studies on the depression guideline. This is a one time solicitation.

RESEARCH OBJECTIVES

Background

A major effort of the AHCPR has been to facilitate the development and dissemination of clinical practice guidelines to help practitioners provide appropriate and effective care. AHCPR-supported guidelines are intended to enhance the quality, appropriateness, and effectiveness of health care. Guidelines have many possible intended and unintended effects. Although guidelines may have many different effects, the RFA is limited to studying the effects around certain specific subjects. A prerequisite to determining practice guidelines' effects on cost, quality and appropriateness of clinical services is to assess their effect on practitioner and patient behavior. Practitioner behavior is therefore an important subject for the RFA. The effect of guidelines on health status and, in particular, on short-term or intermediate health outcomes is also a legitimate topic for projects under the RFA.

Specific Objectives and Methodological Considerations

Applicants may study the effects of one or more of the following AHCPR-supported clinical practice guidelines: (1) Urinary Incontinence in Adults; (2) Early HIV Infection: Evaluation and Management; (3) Sickle Cell Disease: Screening, Diagnosis, Management, and Counseling in Newborns and Infants; (4) Unstable Angina: Diagnosis and Management; and (5) Depression in Primary Care: Detection, Diagnosis and Treatment. Generally, proposed evaluation activities should take the form of experimental or quasi-experimental designs. The evaluation should include pre- and post-intervention measures. A concurrent comparison group not targeted for intervention should be included. The concurrent comparison group need not be insulated from the guidelines, and may receive some information ("attention control"). Alternative

research designs may be considered, but applicants should describe a firm scientific basis for alternative approaches. Applicants should clearly identify the target group(s) who will be the focus of the intervention and the methods by which the guidelines will be introduced.

Research under the RFA should evaluate one or more of the following potential effects of clinical practice guidelines on the delivery of primary care. This may be done in any setting in which the research goal(s) may be met.

- o What are the guidelines' effects on practitioner behavior?
- o What is the effect of the guidelines on practitioner attitudes towards treating or managing the subject disease/condition?
- o What is the effect of guideline implementation on health care service utilization?
- o What is the effect of guideline implementation on health care costs, considering both decreased costs associated with decreasing inappropriate care and increased costs associated with improved detection, recognition, or treatment?
- o What effects do the guidelines have on patient outcomes, health status, quality of life, or satisfaction with care for the condition under study?
- o How can methods to measure the effect of clinical practice guidelines be improved or made more efficient?

An additional question for research under the RFA is the following: how is guideline implementation affected by the type of organization or practitioner with which implementation occurs?

For those evaluating the depression guideline, the following additional questions are suggested:

- o What is the impact of the guideline implementation on the diagnosis, treatment (pharmacological and psychosocial), and the referral of patients suffering from depression?
- o What is the impact of the depression guideline on patients as measured by self report and clinician ratings?

Refer to the RFA for further information on research objectives.

SPECIAL REQUIREMENTS

The issuance of awards will be contingent on the availability of funds and on the quality of the applications. No awards will be made if, as a result of the scientific and technical review, applications are not judged to be of high merit. The initial review committee may recommend support for less than the requested period or amount.

Terms and Conditions of Award

This cooperative agreement anticipates substantial AHCPR/NIMH scientific and programmatic involvement with the awardee(s) throughout the project. The awardee(s) will have primary responsibility for all tasks and activities, including any sampling, protocol development, data collection, data analysis, preparation of publications, community involvement, and liaison with health care providers. The AHCPR/NIMH role in the cooperative agreement will include providing advice in study development; priority setting; establishing two coordinating committees; participation in preparing publications; and disseminating research findings. Refer to the RFA for further information regarding SPECIAL REQUIREMENTS.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the NIH or AHCPR policy on the inclusion of women and minorities in study populations. See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 17, 1994, a letter of intent that includes the name, address, and telephone number of the Principal Investigator, co-investigators and other key personnel; the guidelines selected for evaluation; member institutions, including any other participating organizations or institutions; and the number and title of the RFA. Although a letter of intent is not required, is not binding, and does not enter into the consideration of any subsequent applications, the information allows staff to estimate the potential review workload and avoid conflict of interests in the review. The letter of intent is to be sent to the Dr. James Cooper at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The RFA contains important application information for applicants; see INQUIRIES. The application receipt date is July 21, 1994. Applications are to be submitted on form PHS 398 (rev. 9/91), available at most institutional offices of sponsored research, the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and, for AHCPR applications, from Global Exchange Inc., 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3015, telephone (301) 656-3100 (FAX 301 652-5264).

REVIEW CONSIDERATIONS

Applications will be reviewed initially by the Division of Research Grants, NIH, for completeness, and by AHCPR/NIMH staff for responsiveness to the RFA. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications will be evaluated in accordance with the criteria stated in the RFA for scientific/technical merit by an appropriate peer review group. Further review considerations and special review

criteria are listed in the RFA.

INQUIRIES

Copies of the RFA will be available from: 1) AHCPR InstaFAX (301 594-2800, document 94-0064); and 2) Global Exchange Inc., 7910 Woodmont Ave Suite 400, Bethesda, MD 20814-3015, telephone (301) 656- 3100 (FAX 301 652-5264).

Direct inquiries regarding programmatic issues to:

James Cooper, M.D., Project Officer
Center for General Health Services Extramural Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 502
Rockville, MD 20852-4908
Telephone: (301) 594-1354, ext. 141

Kathy Magruder, Ph.D., M.P.H.
Division of Epidemiology and Services
National Institute of Mental Health
5600 Fishers Lane, Room 10C-06
Rockville, MD 20857
Telephone: (301) 443-3364

Direct inquiries regarding fiscal matters to:

Ralph Sloat
Grants Management Office
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852-4908
Telephone: (301) 594-1447

Bruce Ringler
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance numbers 93.226 and 93.242. Awards are made under authorization of the Public Health Service Act, Title IX and Title IV, Part A (Public Law 78-410 as amended by Public Law 99-158, 42 USC 241 and 285); and administered under the PHS Grants Policy Statement and Federal Regulations 42 CFR 67, Subpart A, 42 CFR 52, and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372.

STUDIES OF THE VIRAL ETIOLOGY OF AIDS-ASSOCIATED MALIGNANCIES

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFA AVAILABLE: CA-94-020

P.T. 34; K.W. 0715008, 0715035, 1002045, 0755030

National Cancer Institute

Letter of Intent Receipt Date: June 17, 1994
Application Receipt Date: July 29, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Cancer Institute (NCI) invites investigator-initiated research grant applications for support of basic studies on the role of viruses and other biological agents in the etiology and biology of malignancies associated with AIDS, including, but not limited to, Kaposi's sarcoma and AIDS-related non-Hodgkin's lymphomas.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Studies of the Viral Etiology of AIDS-Associated Malignancies, is related to the priority areas of cancer and women's health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No.017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No.017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

For-profit and non-profit organizations and institutions, governments and their agencies are eligible to apply. Foreign institutions and organizations are not eligible for the First Independent Research Support and Transition (FIRST) Awards (R29). Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research grant (R01) and the FIRST Award (R29). The total direct cost award for the five-year R29 grant period may not exceed \$350,000 and the direct cost award in any R29 budget period should not exceed \$100,000. Responsibility for the planning, direction and execution of the proposed project will be solely that of the applicant. The total project period for an application for an R01 award submitted in response to this RFA may not exceed five years.

The earliest award date is February 1, 1995. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$1,000,000 in total costs per year for up to five years will be committed to fund applications that are submitted in response to this RFA. It is anticipated that five to six awards will be made.

RESEARCH OBJECTIVES

Patients infected with the human immunodeficiency virus (HIV) are at high risk for the development of opportunistic infections and neoplastic sequelae, particularly Kaposi's sarcoma (KS) and lymphoproliferative diseases such as non-Hodgkin's lymphomas (NHL). KS was once a rare tumor, but a sudden increase was observed in the early 1980s in homosexuals newly diagnosed with AIDS. KS is now diagnosed at initial presentation in nearly 10 percent of AIDS patients. AIDS-KS is characterized by dermal lesions but may progress and result in visceral involvement in the gastrointestinal tract, lungs, and liver. Although the incidence of KS remains fairly constant during the first seven or eight years following HIV infection, it increases in the later stages of AIDS with advancing immune dysfunction and disease progression. Natural history studies indicate that KS develops almost exclusively in homosexual men, suggesting that a sexually transmissible agent(s) may be involved in the etiology of KS. KS is characterized by a proliferation of spindle-like cells, and the lesions are infiltrated by inflammatory cells, fibroblasts and endothelial cells. Cells from KS lesions produce cytokines and growth factors that promote autologous cell growth and the recruitment and growth of normal cells. The HIV tat regulatory protein functions as a growth factor for cultured AIDS-KS cells and tat-transgenic mice develop skin lesions similar to human KS lesions, suggesting tat as a pathogenic link of HIV to KS. However, the mechanism(s) underlying the pathogenesis of this complex tumor is not understood. The etiology of KS has not been established and the factors and mechanisms involved in the growth of KS cells and tissues have not been fully investigated.

Lymphomas are a heterogeneous group of neoplasms observed as lymph node tumors in all population groups of AIDS patients. Tumor development is associated with B-cell activation and oligoclonal proliferation leading to monoclonal or possibly polyclonal expansion of B-cells. The majority of AIDS lymphomas are high grade NHLs, exhibiting aggressive and metastatic growth properties and are refractory to standard therapies. An unusually high rate of extranodal lymphoma occurrence is seen in the central nervous system (CNS), gastrointestinal tract, bone marrow, heart, skin, lung, oral cavity and testis. Approximately 10 to 20 percent of AIDS-NHL are primary CNS tumors, rare in the normal population. These properties suggest that several mechanisms may be responsible for the development of lymphomas in HIV-infected populations. The diversity in the possible etiology of AIDS lymphoid malignancies, in pathology and cell types, and the molecular characteristics of these neoplasms lead to the suggestion that lymphomagenesis in the setting of AIDS may be several distinct disease processes that will require an expanded multidisciplinary research approach. Since the etiology of lymphoid malignancies in the setting of HIV infection is not known, there are opportunities for expanded research.

Two NCI-sponsored workshops were held to address problems and research involving AIDS-associated neoplasms. A workshop entitled "The Biology of AIDS Lymphomas" was held on May 11-12, 1992 in which participants assessed the status of research on AIDS-NHL. An "AIDS-Related Malignancies" workshop was held on January 11, 1993 to stimulate ideas for novel and innovative treatment of AIDS malignancies. This RFA is issued in accordance with the workshop participants' recommendation that extramural research be stimulated in this area with set-aside funds.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 17, 1994, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator(s), the names of other key personnel and collaborators, the participating institutions, and the number and title of the RFA in response to which the application may be submitted.

A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. However, it is requested in order to provide an indication of the number and scope of applications to be reviewed, thus allowing NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Kenneth J. Cremer at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441; and from the NCI Program Director listed under INQUIRIES.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Applications must be received by July 29, 1994. An application received after that date will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique. No addenda or appendix materials will be accepted after the receipt date unless explicitly requested by the Scientific Review Administrator.

REVIEW CONSIDERATIONS

Those applications judged to be both competitive and responsive will be evaluated according to the review criteria stated below for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. A second level of review will be by the National Cancer Advisory Board, which considers the special needs of the Institute and the priorities of the National Cancer Program.

1. The scientific merit, technical and medical significance of the proposed research, including the appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research. Familiarity with the proposed techniques should be demonstrated by the presentation of preliminary data.
2. The demonstrated research experience, expertise and qualifications of the principal investigator and proposed staff and/or collaborators to perform the proposed experiments.
3. Documentation of the adequacy of the facilities and resources necessary to perform the research.
4. Where applicable, the appropriateness of an animal or tissue culture model system chosen for the experiments proposed and the potential relevance of the model system to AIDS-associated malignancies.
5. Where applicable, the demonstration of the availability and access to appropriate human tissue necessary to perform the proposed research, the availability of clinical information associated with human samples, and adequacy of the plans for the inclusion of females and minorities.
6. The adequacy of provisions for the protection of human subjects and the humane treatment of research animals.
7. Appropriateness of the proposed budget and duration in relation to the proposed research.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Kenneth J. Cremer, Ph.D.
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 540
Bethesda, MD 20892
Telephone: (301) 496-6085

Inquiries regarding fiscal matters may be directed to:

Mr. Joseph H. Fitzgerald
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Ext. 215

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.393, Cancer Cause and Prevention Research. Awards are made under the authorization of the Public Health Service (PHS) Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 U.S.C. 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74 or 45 CFR Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

UTERINE BLEEDING AND STEROID HORMONES

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFA AVAILABLE: HD-94-023

P.T. 34; K.W. 0710110, 0760085

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: June 8, 1994

Application Receipt Date: August 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Child Health and Human Development (NICHD) invites research grant applications for the support of investigations into uterine bleeding and steroid hormones that may lead to improved bleeding patterns in women receiving progestin-only contraceptives. A National Institutes of Health/World Health Organization conference held in May 1992 recommended that such studies be conducted (Alexander, N.J., d'Arcangues, C. Steroid Hormones and Uterine Bleeding. 1992. AAAS Press. 344 pp.).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Uterine Bleeding and Steroid Hormones, is related to the priority area of family planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9352 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Minority individuals, persons with disabilities, and women are encouraged to apply.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. The expected award date is April 1, 1995.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

Because the nature and scope of the research proposed in different applications in response to this RFA may vary, the size of each award will vary also.

FUNDS AVAILABLE

It is expected that up to four applications will be funded by the total \$800,000 set aside for the first year. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this RFA is to stimulate research that will lead to a better understanding of the causes of endometrial bleeding induced by exogenous hormones and, with time, the development of effective therapies. Research grant applications may include, but will not be limited to:

- o Defining the characteristics of the endometrial microvascular bed and angiogenesis including growth and repair, as well as the regression of the vascular bed.
- o Defining the characteristics, including the biochemical composition and steroid receptor content, of the sites that may be prone to bleeding.
- o Investigating whether endothelial cells lining endometrial blood vessels differ from endothelial cells of other organs.
- o Determining the morphological and biochemical effect of different steroid regimens including long-term progestin exposure on the capillaries of the superficial epithelium
- o Delineating the distribution of estrogen and progesterone receptors under different steroid regimens
- o Differentiating whether dysfunctional uterine bleeding on certain treatment regimens is a function of unsuppressed ovarian function or exogenous hormones.

o Conducting clinical studies to determine

- 1) whether there are serum markers that can predict the onset of breakthrough bleeding
- 2) if there is an association between blood pressure and dysfunctional bleeding
- 3) whether the causes of bleeding from an atrophic endometrium is different from bleeding that occurs during early phases of progestin-only treatment.

o Studies of a non-human primate model, if one can be found in which relevant studies of steroid induced uterine bleeding are appropriate.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are strongly encouraged, but not required, to submit, by June 8, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NICHD staff to estimate the potential review workload and to avoid conflict of interest circumstances in the review process. The letter of intent is to be sent to Dr. Nancy J. Alexander at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by August 19, 1994. If an application is received after that date, it will be returned to the applicant.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, it will be returned to the applicant, who may then submit it to DRG for review in competition with unsolicited applications at the next available review cycle. Responsive applications may be triaged by a peer review group to determine their relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further evaluation for scientific merit, in accordance with the criteria stated below, by a review committee convened solely for that purpose by the Division of Scientific Review, NICHD. Review criteria for RFAs are generally the same as those for unsolicited research grant applications.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or Principal Investigator could be included with the application.

AWARD CRITERIA

The anticipated date of earliest award is April 1, 1995. Funding decisions will be based on peer review and NACHHD Council recommendations, program relevance, and availability of funds. If the proposed research has relevance to the research program of the National Center for Research Resources (NCRR) as well as that of the NICHD, the application may be dually assigned to, and considered for funding by, the NCRR. Any such assignment will be made independently of peer review procedures.

INQUIRIES

Written and telephone requests for this RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA, inquiries regarding scientific issues, and address the letter of intent to:

Nancy J. Alexander, Ph.D.
Center for Population Research
National Institute of Child Health and Human Development
Building 6100, Room 8B13
Bethesda, MD 20892
Telephone: (301) 496-1661
FAX: (301) 496-0962

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12374 or health Systems Agency review.

CHRONIC FATIGUE SYNDROME COOPERATIVE RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFA AVAILABLE: AI-94-020

P.T. 04; K.W. 0715043, 0710030

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: September 15, 1994

Application Receipt Date: October 25, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Virology Branch (VB) of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) invites applications for the continuation and/or establishment of high-quality Chronic Fatigue Syndrome Cooperative Research Centers (CFS CRCs) that provide a multi-disciplinary, systematic, sustained approach to the study of CFS. A nucleus of CFS CRCs dedicated to use of standardized methodologies and collaborative efforts was established in 1991. This is a recompetition to identify centers with capabilities to build on the initial effort in order to facilitate progress in this difficult research area.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Chronic Fatigue Syndrome Cooperative Research Centers, is related to the priority area of chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local government, and eligible agencies of the Federal government. A strong clinical facility with accessible well-defined CFS patient and control populations is a requirement. Foreign organizations are not eligible to apply. Domestic applications may not include international components. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to continue this program will be the Cooperative Agreement (U01, U19). This type of funding mechanism is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Institutes of Health (NIH) and when substantial programmatic assistance by NIH staff is anticipated. Details of the responsibilities, relationships, and governance of a study funded under a cooperative agreement are discussed in the RFA under the section TERMS AND CONDITIONS OF AWARD. Awards will be made to an institution on behalf of a CRC Director (principal investigator) who will be responsible for the coordination of CFS CRC scientific and administrative activities.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards under this RFA will be \$1.6 million. The NIAID plans to make at least three competing continuation and/or new awards under this RFA. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Awards will be made for a project period of up to four years. Funding beyond the first and subsequent years of the award will be contingent upon satisfactory progress during the preceding years and upon availability of funds.

RESEARCH OBJECTIVES

Chronic fatigue syndrome (CFS) is a multisystem syndrome thought to be triggered by viral infection and characterized by months of debilitating fatigue frequently associated with myalgia, headache, sore throat, low grade fever, gastrointestinal symptoms, and tender lymph nodes. There have been reports of immunologic and, more recently, neuroendocrine parameters in CFS patients that on a group basis are different from those in healthy controls, but no single immunologic or neuroendocrine marker can be used to diagnose the syndrome. The cause and pathogenic mechanisms of the illness are unknown.

The purpose of this RFA is to support a network of clinical centers of research excellence that use standardized methods for patient enrollment and data collection to pursue multidisciplinary coordinated projects to study etiology, natural history and/or pathogenesis of CFS. Expertise in fields of medicine, immunology, virology, physiology, psychology, clinical anthropology or clinical epidemiology may be helpful in furthering our understanding of CFS. It is not expected that expertise in all these areas be available at a single institution. Input from the NIAID Scientific Coordinator will facilitate technology transfer, assist in the identification of expert consultants, collaborators and resources, enhance communication between awardees and help to ensure that pilot studies funded through the program will complement and not unnecessarily duplicate existing or planned CFS research endeavors.

Well-designed studies with adequate sample sizes are needed to test biologically rational hypotheses concerning etiology or pathogenesis that will lead to improved diagnosis and effective interventions. Originality in concept and approach is encouraged. The development, standardization and evaluation of clinical status and outcome measures for use in CFS therapeutic trials comprise another potential area for study. Medically and statistically sound therapeutic studies may be appropriate for testing certain hypotheses regarding pathogenesis, but it is not the intent of this RFA to support large-scale treatment trials.

Budget and Related Issues

In addition to support for personnel, supplies, travel to an annual CFS CRC workshop and other necessary costs justified in the application for conducting CRC research projects, award funds may be utilized to support the following research-related activities:

- o **SHARED RESEARCH RESOURCES:** Funds for administration, equipment, supplies and services to expand and/or maintain clinical, laboratory, biostatistical and data management facilities which are shared by research staff from at least two CRC research projects.

- o **DEVELOPMENTAL FUND FOR PILOT STUDIES:** Applicants may request that a limited pool of funds, not to exceed \$40,000 in direct costs annually, be made available for pilot projects. This Developmental Fund would be set aside and restricted solely to cover salaries and other research costs for small pilot studies to follow-up on new observations and novel hypotheses. Such pilot studies need not be restricted to the awardee institution. Detailed information about the Developmental Fund will be provided in the complete RFA.

- o **PATIENT CARE COSTS:** Budget requests may also include research-related costs for patient involvement.

- o **BIOSTATISTICAL SUPPORT:** The budget should include adequate biostatistical support to ensure sound study design, data collection and data analysis procedures.

SPECIAL REQUIREMENTS

The RFA describes the complete terms for this cooperative agreement including definitions, terms and conditions of award, responsibilities of the awardees, responsibilities of NIAID staff, collaborative responsibilities and the arbitration process to resolve disputes. The RFA is available from the Program Director listed under INQUIRIES.

STUDY POPULATIONS

Cases must be enrolled using clearly specified inclusion and exclusion criteria comparable with those detailed in the consensus documents prepared by the Centers of Disease Control and the National Institutes of Health (Holmes, et al., Annals of Internal Medicine: 108, 387-389, 1988; Schluederberg, et al., Annals of Internal Medicine: 117, 325-331, 1992). More details are provided in the RFA under SPECIAL REQUIREMENTS.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details. Copies of these Guidelines may be obtained from Dr. Schluederberg (listed in INQUIRIES below).

LETTER OF INTENT

Prospective applicants are asked to submit, by September 15, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the Principal Investigator, the number and title of this RFA, and a list of the key investigators and their institution(s). The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES. This letter of intent is not required, is not binding, and does not enter into the review of subsequent applications.

APPLICATION PROCEDURES

Applications are to be submitted on the research grant application form PHS 398 (rev. 9/91). These application forms may be obtained from the institution's office of sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "CFS COOPERATIVE RESEARCH CENTERS" must be typed in. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

Applications must be received October 25, 1994, and sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID staff to determine responsiveness to this RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration or review. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant and the institutional business official. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by an appropriate review committee convened by the NIAID. A second level of review will be provided by the NIAID Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues and requests for the RFA to:

Ann Schluederberg, Sc.D.
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A16
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7453
FAX: (301) 496-8030

Direct inquiries regarding review procedures, address the letter of intent to, and mail two copies of the application and all five sets of appendices to:

Olivia Preble, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C20
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8208
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Victoria Putprush
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B28
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

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| Letter of Intent Receipt Date: | September 15, 1994 |
| Application Receipt Date: | October 25, 1994 |
| Scientific Review Date: | February 1995 |
| Advisory Council Date: | June 1995 |
| Earliest Award Date: | September 1995 |

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Diseases Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RFA AVAILABLE: AI-94-021

P.T. 34; K.W. 0715013, 0715110, 0715120

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: August 15, 1994

Application Receipt Date: November 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTS IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATIONS, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Allergy, Immunology and Transplantation (DAIT), National Institute of Allergy and Infectious Diseases (NIAID), invites applications for Asthma, Allergic and Immunologic Diseases Cooperative Research Centers (AAIDCRCs). This program is designed to support basic and clinical research on mechanisms of, intervention in, and prevention of asthma, allergic and immunologic diseases. Applications are to be designed around a central scientific theme demonstrating relevance to one or more diseases in these areas. A minimum of three biomedical research projects must be proposed, plus a Demonstration and Education (D&E) research component to study interventions for asthma, allergic and/or immunologic diseases in defined populations.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Asthma, Allergic and Immunologic Diseases Cooperative Research Centers, is related to the priority areas of education and community-based programs, environmental health, diabetes and chronic disabling conditions, and immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Foreign organizations are not eligible to apply. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to undertake this program will be the Multiproject Cooperative Agreement (U19). The total project period for applications submitted in response to this RFA may not exceed four years. Reissuance of this initiative in future years is anticipated, but not certain. If by the beginning of the last year of support, the NIAID has not announced intentions to readvertise the RFA, incumbents who wish to recompete are strongly encouraged to contact NIAID Program Staff concerning selection of an appropriate research mechanism before reapplying.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards made under this RFA will be \$3,000,000. In Fiscal Year 1995, the NIAID plans to fund approximately four U19s. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

Scope of the Biomedical Research Component: Eligible topics for study relevant to asthma, allergic and immunologic diseases may include, but are not limited to, the following. Studies of the Human Immunodeficiency Virus (HIV), AIDS, and associated opportunistic infections and malignancies are not encompassed under this RFA.

- o basic pathophysiologic mechanisms of human asthma and/or allergic diseases, such as the role of cytokines, T cell subsets and/or adhesion molecules in asthmatic and allergic inflammation and IgE responses;
- o identification, isolation and characterization of etiologic agents of allergic and hypersensitivity reactions (e.g., airborne allergens, drugs, industrial chemicals, foods and contact sensitizing agents);
- o epidemiology and genetics of allergic diseases (including allergic rhinitis, asthma, and atopic dermatitis);
- o strategies for, and mechanisms of, prevention of asthma, allergic or immunologic diseases;
- o pathophysiology of other hypersensitivity reactions (including allergic bronchopulmonary aspergillosis, hypersensitivity pneumonitis, food allergy and drug reactions);
- o mechanisms of immunodermatologic diseases (many hypersensitivity and immune-mediated inflammatory mechanisms are relevant to disorders of the skin such as contact dermatitis, atopic dermatitis and urticaria);

- o genetic, cellular and molecular mechanisms of immune system disorders including autoimmune diseases and immunodeficiency diseases, but excluding AIDS;
- o application of immunotherapeutics to immune system disorders;
- o characterization of mechanisms of acute and chronic inflammation;
- o immunopathologic aspects of host defense and phagocytosis; and
- o normal and abnormal leukocyte and complement system functions.

Scope of the Demonstration and Education (D&E) Research Component: Examples of diseases, populations, and types of interventions of interest include, but are not limited to the following. Efficacy studies of specific drugs/treatments are not encompassed under the D&E component of this RFA.

Diseases: (1) asthma, including both host and environmental factors; (2) allergic diseases, including allergic rhinitis, atopic dermatitis, contact dermatitis, urticaria, food and drug allergies; and (3) immunologic diseases, including autoimmune diseases, including systemic lupus erythematosus, diabetes, and rheumatoid arthritis, immunodeficiency diseases and chronic inflammatory disorders.

Defined Populations: Although asthma, allergic and immunologic diseases afflict many populations, particular interest is focused on populations that are disproportionately affected by these disorders, including children; the elderly; women; minorities; as well as urban and rural populations.

Types of Interventions: A broad range of interventions may be proposed for testing, including medical, behavioral, environmental, and educational. A variety of settings may be considered, including school-based, clinic-based, and community-based. Interventions may be targeted to patients, their families, health care providers, health care institutions, and/or the community.

D&E Study Design: Scientific direction and coordination for the D&E research projects will be provided by the AAIDCRC Steering Committee, composed of the AAIDCRC Director, the D&E Research Project Leaders, and the NIAID Scientific Coordinator. D&E research projects will be selected by the Steering Committee from among those judged to be scientifically meritorious by the Initial Review Group.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 15, 1994, a letter of intent that includes a descriptive title of the overall proposed research, the name, address and telephone number of the AAIDCRC Director, the number and title of this RFA, a list of the names of key investigators and their institution(s), and a descriptive title of each proposed research project. The letter of intent is to be sent to Dr. Mark Rohrbaugh at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be prepared using the guidance and instructions provided in the information brochure, NIAID INFORMATION BROCHURE ON PROGRAM PROJECT GRANTS AND MULTIPROJECT COOPERATIVE AGREEMENTS (rev. February 1994), which may be requested along with the RFA, from the program staff listed under INQUIRIES.

Applications are to be submitted on the research grant application form PHS 398 (rev. 9/91). These application forms may be obtained from most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. Applications must be received by November 15, 1994. For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "Asthma, Allergic and Immunologic Diseases Cooperative Research Centers" must be typed in.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the NIH Division of Research Grants (DRG) and for responsiveness by NIAID staff. Incomplete and non-responsive applications will be returned to the applicant without further consideration. Those applications that are complete and responsive may be subjected to a triage by a peer review group to determine their scientific merit relative to other applications received in response to this RFA. The NIAID will withdraw from competition those applications judged to be non-competitive for award and will notify the Principal Investigator and institutional business official. Those application that are non-competitive will receive an abbreviated Summary Statement. Those applications judged by the reviewers to be competitive for award will be further reviewed for scientific and technical merit by a review committee convened by the Division of Extramural Activities, NIAID. The second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council.

General review criteria used for multiproject cooperative agreement applications are outlined in the information brochure, NIAID PROGRAM PROJECT GRANTS AND MULTIPROJECT COOPERATIVE AGREEMENTS. Additional criteria specific to this program are presented in the RFA.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program needs and balance, and the availability of funds.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues, requests for the RFA, the NIAID Information Brochure on Program Project Grants and Multiproject Cooperative Agreements, and the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," to:

Marshall Plaut, M.D.
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A23
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8973
FAX: (301) 402-2571

Direct inquiries regarding review issues, address the letter of intent to, and mail two copies of the application and five sets of appendices to:

Mark Rohrbach, Ph.D.
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C22
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8424
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Louis Kreh
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B26
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

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| Letter of Intent Receipt Date: | August 15, 1994 |
| Application Receipt Date: | November 15, 1994 |
| Scientific Review Date: | February 1995 |
| Advisory Council Date: | June 1995 |
| Earliest Award Date: | August 1995 |

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.855 - Immunology, Allergy and Transplantation Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

BASIC RESEARCH IN EMOTION

NIH GUIDE, Volume 23, Number 16, April 29, 1994

PA AVAILABLE: PA-94-059

P.T. 34; K.W. 0715095, 0414000

National Institute of Mental Health
National Institute on Aging
National Institute of Child Health and Human Development

THIS IS A NOTICE OF AVAILABILITY OF A PROGRAM ANNOUNCEMENT (PA); IT IS ONLY AN ABSTRACT OF THE PA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE PA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE PA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

Under this program announcement, the National Institute of Mental Health (NIMH), the National Institute on Aging (NIA), and the National Institute of Child Health and Human Development (NICHD) invite research grant applications to expand basic research on the processes and mechanisms involved in the experience and expression of emotion.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Basic Research in Emotion, is related to the priority area of mental health and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by public and private non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, research institutions, units of State or local governments, and eligible agencies of the Federal Government. Foreign institutions are not eligible for First Independent Research Support and Transition Award (FIRST) (R29) awards. Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

In order to encourage increased research, applications are requested under the following mechanisms: research project grant (R01), small grant (R03, NIMH only), and FIRST award (R29). Eligibility and requirements for different funding mechanisms vary. Applicants are advised to contact NIMH, NIA, or NICHD program staff listed under INQUIRIES for additional information and specific application procedures.

For research in method development, the small grant (R03) is a particularly appropriate mechanism; investigators may also choose to include method development as one component within research project grant (R01) applications.

Support may be requested for a period of up to five years, except for small grants (R03) which are limited to two years. FIRST awards must be requested for five years. Annual noncompeting awards will be made subject to continued availability of funds and progress achieved.

RESEARCH OBJECTIVES

After many years of psychological and psychiatric inquiry that paid little attention to the empirical study of emotion, the field of emotion has now begun to coalesce. An empirical foundation exists for the investigation of basic research questions that lie at the core of understanding normative behavior and function, as well as mental disorder, its treatment, and prevention.

Research goals and needs are described in six categories: basic mechanisms of emotion; individual differences; developmental aspects; social aspects; biological aspects; and methodological needs. Sample research questions are provided in the program announcement for illustrative purposes; they are not intended to be exhaustive.

STUDY POPULATIONS**INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS**

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the PA for details.

APPLICATION PROCEDURES

Applicants are to use grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The number and title of this program announcement, PA-94-059, Basic Research in Emotion, must be typed in item number 2a on the face page of the PHS 398 application form.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and returned without review.

Non-AIDS research applications (R01, R29, R03) will be accepted at the standard application deadlines as indicated in the application kit. The receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

REVIEW CONSIDERATIONS

Applications received under this program announcement will be assigned to an initial review group (IRG) in accordance with established PHS referral guidelines. The IRGs, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Following scientific-technical review, applications (except those for small grants) will receive a second-level review by the appropriate National Advisory Council.

AWARD CRITERIA

Applications recommended by the appropriate national advisory council will be considered for funding on the basis of overall scientific and technical merit of the research, as determined by peer review, Institute program needs and balance, and availability of funds.

This program announcement focuses on areas of interest across NIMH, NIA, and NICHD research divisions and programs. Application assignments will be made based on established referral guidelines.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Address inquiries regarding programmatic issues to:

Lynne C. Huffman, M.D.
Division of Neuroscience and Behavioral Science
National Institute of Mental Health
5600 Fishers Lane, Room 11C-10
Rockville, MD 20857
Telephone: (301) 443-3942
FAX: (301) 443-4822
E-mail: L3H@NIHCU.BITNET

Ronald P. Abeles, Ph.D.
Behavioral and Social Research Program
National Institute on Aging
Gateway Building, Room 533
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-3136
FAX: (301) 402-0051
E-mail: RAS@NIHCU.BITNET

Sarah L. Friedman, Ph.D.
Human Learning and Behavior Branch
National Institute of Child Health and Human Development
Building 6100, Room 4B05
Bethesda, MD 20892
Telephone: (301) 496-6591
FAX: (301) 402-2085
E-mail: SF2@NIHCU.BITNET

Address inquiries regarding fiscal matters to:

Diana Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

Vicki Maurer
Grants Management Office
National Institute on Aging
Gateway Building, Room 2N-212
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1472

Donald Clark
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Blvd., Room 8A01C
Rockville, MD 20852
Telephone: (301) 496-5001

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.242, 93.281, 93.282, 93.865, and 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 42 CFR Part 66. This program announcement is not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100, or Health Systems Agency review.

RESEARCH ON METHODS IN MENTAL HEALTH RESEARCH

NIH GUIDE, Volume 23, Number 16, April 29, 1994

PA NUMBER: PA-94-060

P.T.

National Institute of Mental Health

PURPOSE

The purpose of this program announcement is to encourage research grant applications for work on the design, measurement, and statistical challenges inherent in conducting mental health research. The goal of this initiative is to build the methodological infrastructure of mental health research by encouraging statisticians, psychometricians, and other experts in research methodology and data analysis to focus on these challenges.

This program announcement addresses recommendations set forth in the Clinical Services Research section of Caring for People with Severe Mental Disorders: A National Plan of Research to Improve Services and in earlier National Institute of Mental Health (NIMH) initiatives relating to specific populations and disorders, including children and adolescents, the elderly, rural populations, and schizophrenia.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This program announcement, Research on Methods in Mental Health Research, is related to the priority area of mental health and mental disorders. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Research support may be requested through applications for regular research grants (R01), small grants (R03), and FIRST awards (R29). Since the R03 and R29 mechanisms have special requirements regarding eligibility, application format, and review criteria, applicants are strongly encouraged to consult with program staff (listed under INQUIRIES) and obtain specialized announcements.

Applications may request support for up to five years for regular research. Small grants are limited to two years and may not be renewed. FIRST awards are for five years, but are not renewable. Annual awards will be made, subject to continued availability of funds and progress achieved.

Because the nature and scope of the research proposed in response to this program announcement will vary, it is anticipated that the size of the awards will also vary.

RESEARCH OBJECTIVES

Background. Advances in mental health research are highly dependent on the quality of research procedures, measures, and data analytic strategies available to investigators. As the knowledge base broadens and deepens, questions of increasing subtlety and complexity must be addressed. To do so requires the development or adaptation of increasingly more sophisticated and precise methods, measures, and analytic strategies.

The NIMH is issuing this program announcement to ensure that statisticians, psychometricians, and other experts in research methodology and data analysis who are currently working on the methodological issues in mental health research will continue to do so and that those methodological experts who are not working on mental health issues will be encouraged to enter the field, bringing with them the insight that a fresh perspective can provide in finding solutions to problems.

This program announcement makes explicit the determination of NIMH to support the basic methodological work necessary for the advancement of mental health research.

Research Issues. Listed below are examples of research topic areas that focus on methods, measurement, and statistical analysis in mental health research. The list of examples is illustrative, not exhaustive; it is expected that additional important research topics will be identified by researchers who respond to this program announcement. Design, measurement, and data analytic topics relevant to any of the areas of inquiry funded by NIMH, including mental health

services, epidemiologic, prevention, basic behavioral, brain, and clinical and treatment research, are encouraged.

- o Studies focusing on the development and refinement of instruments and procedures for assessing both stable and unstable characteristics of individuals (e.g., psychopathology, mental disorder, positive/adaptive personality functioning) and environments (e.g., stressful and supportive conditions of home, workplace, social networks, service systems), with particular attention to psychometric indices of reliability and validity, including susceptibility to response bias, gender differences, cultural relevance, and applicability to diverse study populations
- o Research concerning the development of new or improved data analytic strategies for handling the difficulties and challenges encountered in analyzing data from longitudinal studies
- o Research to develop design, assessment, and data analytic methods that address the shortcomings, for clinical decision making, of sample-based statistical conclusions
- o Studies bearing on the use and/or combination of data from multiple informants, including attention to (1) individual characteristics and environmental context, and (2) how the influences of these factors change as a function of the nature of the information reported
- o Studies of the reliability and validity of instruments in multiple outcome domains particularly for understudied populations, e.g., severely mentally ill persons who are homeless, minorities, rural residents, and severely emotionally disturbed children

STUDY POPULATIONS

INCLUSION OF FEMALES AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applicants are to use the research grant application form PHS 398 (rev. 9/91). The number (PA-94-060) and the title of this program announcement, Research on Methods in Mental Health Research, must be typed in item number 2a on the face page of the PHS 398 application form. Applicants must also specify under which support mechanism they are applying: R01, R29, R03.

Applicants should note that FIRST (R29) applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Application kits containing the necessary forms may be obtained from the office of sponsored research at most universities, colleges, medical schools, and other major research facilities or from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

The signed original and five copies of the completed PHS 398 must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be reviewed for scientific and technical merit by an initial review group (IRG) composed primarily of non-Federal scientific experts. Final review is by the appropriate National Advisory Council; review by Council may be based on policy considerations as well as scientific merit. By law, only applications recommended for consideration for funding by the Council may be supported. Summaries of IRG recommendations are sent to applicants as soon as possible following IRG review.

Review Criteria. Criteria to be considered in evaluating R01 applications for scientific/technical merit include:

- o Scientific, technical, or medical significance and originality of the proposed research
- o Appropriateness and adequacy of the research approach and methodology proposed to carry out the research
- o Qualifications and research experience of the principal investigators and staff, particularly but not exclusively in the area of the proposed research
- o Availability of resources necessary to the research
- o Appropriateness of the proposed budget and duration in relation to the proposed research
- o Adequacy of the proposed means for protecting against or minimizing adverse effects to human and/or animal subjects

Because the R03 and R29 mechanisms have some distinct review criteria, applicants are strongly encouraged to consult with program staff (listed under INQUIRIES) and obtain specialized announcements.

AWARD CRITERIA

Factors considered in determining which applications will be funded include IRG and Council recommendations, PHS program needs and priorities, and availability of funds.

As part of the NIMH Public-Academic Liaison (PAL) initiative, preference may be given to applications that involve active collaborations between academic researchers and public sector agencies in planning, undertaking, analyzing, and publishing research pertaining to persons with severe mental disorders. The PAL initiative is based on the premise that important new advances in understanding and treatment of severe mental disorders can result from improved linkages between the Nation's scientific resources and the public sector agencies and programs in which many persons with severe mental disorders receive their care.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Ann A. Hohmann, Ph.D., M.P.H.
Services Research Branch
National Institute of Mental Health
5600 Fishers Lane, Room 10C-06
Rockville, MD 20857
Telephone: (301) 443-3364

Direct inquiries regarding fiscal matters to:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.242. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285). Grants must be administered in accordance with the PHS Grants Policy Statement (Rev. October 1990). Federal Regulations at 42 CFR Part 52 and 66, "Grants for Research Projects" and 45 CFR Parts 74 [and 92 when applicable for State and local government.] This program is not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100, or Health Systems Agency review.

SCHOOL-BASED PREVENTION INTERVENTION RESEARCH

NIH GUIDE, Volume 23, Number 16, April 29, 1994

PA NUMBER: PA-94-061

P.T.

National Institute on Drug Abuse

PURPOSE

The purpose of this program announcement is to encourage the scientific study of drug abuse prevention strategies that are based in the school environment to determine their efficacy in preventing the initiation of drug use and dependent patterns of drug abuse. Two major types of research are included under this program announcement: new innovative, theory-based school-based programs/curricula; and, the evaluation of existing school-based programs/curricula that have been well-established within schools for a number of years. Research must include both process and controlled outcome studies and must examine the relationship between process and outcome. Where possible, impact measures should be included. Process studies examine the extent to which the program has been implemented as designed. Outcome studies assess the extent to which the programs have achieved their desired effects. These studies should focus not only on drug use behaviors but also on those behavioral, attitudinal, cognitive, and environmental factors that are to be influenced by the intervention. Finally, impact studies analyze the extent to which the programs have altered drug use practices at the school, neighborhood or community level. Follow-up analyses should emphasize the relationship between the mediating variables and drug usage patterns. Studies focused upon rural and inner city schools are encouraged.

HEALTH PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, School-based Prevention Intervention Research, is related to the priority area of alcohol and other drug abuse. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, research institutions, units of State or local governments, and eligible agencies of the Federal government. Applicants from minority individuals and women are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) Awards.

MECHANISMS OF SUPPORT

Support mechanisms include research projects grants (R01), small grants (R03), FIRST awards (R29), and program projects (P01). Because the nature and scope of the research proposed in response to this program announcement may vary, it is anticipated that the size of an award will also vary.

RESEARCH OBJECTIVES

The goal of this program announcement is to invite applications from researchers who wish to study the efficacy and effectiveness of school-based interventions. The specific objectives of this research program are to promote research studies that examine the relationship between theory-based prevention intervention strategies and drug using behaviors with special emphasis on delineating the effects of these interventions on one or more of the following domains: cognitive, affective/interpersonal, behavioral, environmental/policy, and therapeutic as discussed below.

Cognitive preventive strategies focus primarily on increasing the target population's knowledge of the pharmacologic effects and physical/social consequences of drug use and abuse, and on establishing attitudes and belief structures that are supportive of a drug-free lifestyle.

Prevention strategies that include affective and interpersonal factors attempt to strengthen children's inner emotional and psychological resources by improving feelings of self-concept and self-worth and by assisting children to become more aware of their own feelings and those of others. Although these intervention strategies may not directly target drug using behaviors per se, their underlying premise is that by focusing on children's psychological development, the potential for involvement with drugs will be minimized.

The foundation of behavioral intervention strategies are the philosophy and tools of behavioral therapy. Through these interventions children are taught resistance scenarios and skills to prevent involvement in drug using behaviors. Six steps usually form the program: instruction and coaching in resistance techniques, modeling of the desired behaviors by peers, guided practice and role playing, feedback from peers and instructors, social reinforcement through praise, and training for generalization of the new skill to the children's natural environment.

Environmental/policy strategies include school management activities to deal with student drug problems. These would include the implementation of school drug policies, drug-free school zones, and may involve parents and community agencies such as the police department. The impact on drug abuse and related behaviors of recent efforts to re-tool school environments (for example, by involving parents in classrooms, by increasing the use of schools for non-academic activities, and by encouraging supportive interactions among students about academic and non-academic problems) could also be studied.

Finally, therapeutic strategies are designed for children who are already experiencing adjustment problems in school, the family, and, the community. These programs focus on early identification and referral and may also include alternative day school learning environments. The purpose of these programs is to keep children in school as long as possible while at the same time providing needed therapy in the form of special educational modules and individual and group counselling.

A variety of techniques should be employed to realize the aims of these intervention approaches including peer group discussions, special classroom activities, dissemination of policy guidelines, special parent and community organizations, and, individual and group counselling. Both the intensity and methods of these interventions need to be evaluated with respect to immediate effectiveness in intervening factors (cognitive, behavioral, affective/interpersonal, environmental/policy and therapeutic) and to long-term drug using behaviors.

Further study is needed to identify and determine the effects of risk and protective factors. Studies that assess long-term effects need to be carried out. The relationship between process and outcome requires examination. The effect of various strategies in combination with other strategies needs additional investigation.

Health Services Research

Research specifically targeted toward determining the effectiveness of school-based drug prevention programs as part of the health care services system is encouraged. These studies should assess the effectiveness of drug prevention programs under real world conditions.

Prevention Research in Rural Communities

Drug prevention research within rural communities is encouraged. Studies are needed to determine the efficacy and effectiveness of drug prevention programs uniquely suited to the needs of youth and young adults living in rural America.

Research should ultimately address these questions:

- o what is the validity of the theoretical basis of the intervention?
- o does the intervention achieve the desired effects?
- o to what extent are these effects achieved?
- o for whom is the intervention most effective?
- o what process factors are associated with positive outcomes?
- o what is the cost effectiveness/cost benefit of the intervention?

Application characteristics should include:

- o Specification of a theoretical or conceptual framework for the intervention and associated hypotheses
- o Specification of the intervention strategy being studied
- o Involvement of some community segment or agency as part of the intervention
- o Specification of target populations and intent of the intervention, e.g., knowledge, resistance skills, improved academic competence, measures of increased school/family/community bonding
- o Clarity as to the sampling unit and unit of analysis
- o Experimental or quasi-experimental research designs
- o Specification of period of follow-up both of the intervention and of the data collection effort
- o Identification of tracking and follow-up into the "at risk" years, i.e., late adolescence, early adulthood

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 9, 1994 (FR 59 11146- 11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines indicated in the application kit. Receipt dates for applications for AIDS-related research are found in the PHS 398 instructions.

Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of this program announcement must be typed in Item 2a on the face page of the application form PHS 398.

FIRST applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

Other NIDA program announcements may be obtained from the Grants Management Branch, National Institute on Drug Abuse, 5600 Fishers Lane, Room 8A54, Rockville, MD 20857, telephone 301/443-6710.

The completed original and five legible copies of the application form PHS 398 must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be reviewed for scientific and technical merit by initial review groups in accordance with the standard NIH peer review procedures. Following the scientific-technical review, the applications will receive a second-level review by the appropriate national advisory council. Small grant applications (R03) do not receive a second-level review.

AWARD CRITERIA

Applications will compete for available funds with all other applications assigned to the NIDA. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review;
- o Availability of funds; and
- o Program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Larry A. Seitz, Ph.D.
Division of Epidemiology and Prevention Research
National Institute on Drug Abuse
Parklawn Building, Room 9A53
5600 Fishers Lane

Rockville, MD 20857
Telephone: (301) 443-1514

Direct inquiries regarding fiscal matters to:

Gary P. Fleming, J.D., M.A.
Grants Management Branch
National Institute on Drug Abuse
Parklawn Building, Room 8A54
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Awards are made under authorization of Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal Regulations at Title 42 CFR Part 52, "Grants for Research Projects," Title 45 CFR part 74 & 92, "Administration of Grants," and 45 CFR Part 46, "Protection of Human Subjects." Title 42 CFR Part 2 "Confidentiality of Alcohol and Drug Abuse Patient Records" may also be applicable to these awards. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Sections of the Code of Federal Regulations are available in booklet form from the U.S. Government Printing Office. Awards must be administered in accordance with the PHS Grants Policy Statement (rev. 10/90), which may be available from your office of sponsored research.

ENVIRONMENTAL AGENTS AND ASTHMA

NIH GUIDE, Volume 23, Number 16, April 29, 1994

PA NUMBER: PA-94-062

P.T. 34; K.W. 0715013, 1007003

National Institute of Environmental Health Sciences
National Institute of Allergy and Infectious Diseases
National Heart, Lung, and Blood Institute

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Heart, Lung, and Blood Institute (NHLBI) invite applications to support research to determine the relationships between exposure to environmental pollutants and allergens and the induction and/or exacerbation of asthma in humans and to define the mechanisms by which such environmental agents contribute to the disease process of asthmatics.

The NIEHS is the principal Federal funding component to support research scientifically examining the basic mechanisms by which exposure to physical and chemical agents in the environment have deleterious effects on human health and exacerbate human health problems. Many of these agents are airborne substances that contribute to and/or exacerbate asthma and atopic diseases in susceptible individuals. The knowledge of mechanisms by which these agents act will provide the sound scientific basis on which to develop therapeutic and prophylactic measures for the treatment and control of these environmentally-induced health problems.

The NIAID is the principal Federal funding component that supports fundamental research concerned with the structure and function of the immune system in health and disease. The acquisition of new and deeper knowledge about the immune system is requisite to the development of improved procedures for prevention, diagnosis, and treatment of immunological diseases and diseases having a major immunological component such as asthma and atopic diseases.

The NHLBI is the principal funding component that supports research concerned with the structure and function of the pulmonary system in health and disease. The acquisition of new knowledge on the impact of inhaled agents on the respiratory system and their role in the pathogenesis and exacerbation of asthma is requisite to developing methods for early diagnosis and prevention of disease as well as to developing new methods for treatment. The research mission of the NHLBI extends to health education and outreach programs to examine the environmental impact on lung complications from asthma.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Environmental Factors and Asthma, is related to the priority areas of environmental health and diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Foreign institutions are not eligible to apply for the First Independent Research Support and Transition (FIRST) Award (R29).

MECHANISM OF SUPPORT

The mechanisms of support will be the individual research project grant (R01) and the FIRST Award (R29). Multidisciplinary approaches that involve collaborative efforts among investigators in the fields of basic and clinical immunology, allergy, pulmonology, biochemistry and molecular biology are strongly encouraged. Policies that govern research grant programs of the National Institutes of Health will prevail.

RESEARCH OBJECTIVES

Background

Asthma is a clinical condition, the symptoms of which include intermittent shortness of breath and wheezing, chest tightness and cough. This condition is usually reversible either spontaneously or as a result of treatment. Asthma may be caused or provoked by exposure to airborne pollutants encountered in the general environment or the workplace. Asthma is a common cause of morbidity and disability, affecting an estimated two to five million children and 20 million individuals in the USA. Morbidity associated with asthma accounts for an estimated 8.5 million physician and emergency room visits annually; this translates into an estimated one million work days lost that are related to asthma-associated disability.

A large number of agents in the environment and workplace have been shown to induce asthma and asthma-like syndromes. Although the proportion of asthma cases and asthma-like illness attributable to environmental and occupational exposure is currently unknown, evidence is accumulating that the inhalation of ozone, sulfuric acid, and nitric acid, by individuals with allergic asthma, significantly affects their respiratory capacity by decreasing lung volume and peak flow. The mechanisms responsible for pollutant-induced asthma are uncertain and the appropriate pharmacologic interventions are unknown.

A recent report by the Institute of Medicine, supported by the NIAID, NIEHS, NHLBI and EPA, entitled "The Health Effects of Indoor Allergens," highlighted the role of indoor allergens in asthma and provided directions for research to explore this area. The report reviews recent data suggesting that indoor allergens, notably those derived from dust mite, cat, and cockroach, are critical factors in the etiology of asthma, and that individuals spend the vast majority of their time in an indoor environment, presumably exposed to these allergens. Indeed, one important, but unproven, theory suggests that asthma is increasing in prevalence because of changes in house construction that have made homes "tight," resulting in increased levels of indoor allergens as well as of other environmental agents (e.g., irritants such as wood smoke and environmental tobacco smoke). Outdoor pollutants are relevant as well, since such molecules as ozone and oxides of nitrogen and sulfur are also present indoors. It is possible that irritants and pollutants act synergistically with allergens. The relative importance of these environmental agents are unknown, but there are several examples of possible interactions between irritants/pollutants and allergens for influencing both airway hyperreactivity and immune responses. Ozone and sulfur dioxide, as mentioned above, are reported to worsen asthma and increase bronchial hyperreactivity. In animal models these pollutants (and nitrogen oxides) are said to increase IgE antibody production. Diesel exhaust particulates apparently enhance IgE antibody production to allergens. Environmental tobacco exposure not only reduces pulmonary function, but also appears to enhance IgE antibody production to allergens. The physicochemical nature of particulates in the air also are said to regulate IgE antibody production, perhaps because size, charge, and other properties influence allergen binding and processing. However, the mechanisms by which these events occur have not been well characterized. Thus, this initiative represents a joint effort by NIEHS, NIAID, and NHLBI to foster research programs to determine such relationships between exposure to environmental pollutants and allergens and the induction and/or exacerbation of asthma in humans.

Research Goals and Scope

Areas of research that would be responsive to this Program Announcement should be focused on mechanistic studies, with both basic and preclinical investigation, involving animal models, cultured human cell models, and human patients. These areas may include, but are not limited to:

- o Evaluation of the role of pollutants (including environmental tobacco smoke, diesel particulates, oxides of nitrogen and sulfur, and others), in conjunction with allergen on both IgE antibody production to allergen, and expression of clinical disease.
- o Examination of the effects of removal of pollutants and/or allergen avoidance on reducing IgE antibody responses and preventing clinical disease.
- o Defining the relationship between pollutant-mediated airway hyperreactivity and allergen-mediated airway hyperreactivity.
- o Defining the relationship between outdoor allergens and other environmental agents in the development and exacerbation of asthma.
- o Determining what differences between indoor and outdoor allergens (and environmental factors such as pollutants) explain why indoor allergen sensitivity correlates with asthma while outdoor allergen sensitivity correlates with allergic rhinitis.
- o Determining the manner in which pollutants interact with viral respiratory infections in the induction of asthma.
- o Determining the basic mechanisms by which pollutants alter the inflammatory response in the airways, resulting in airways hyperreactivity, IgE antibody production and asthma. These studies could concentrate on the response mechanism which may occur through the modulation of neural function, epithelial cell function, antigen-presenting cell function, inflammatory cell function, mediators, cytokines, receptor modulation, and/or signalling pathways which may be involved in the pathogenesis of asthma.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy for the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

Animal Welfare Considerations

Investigators are encouraged to consider alternative methods and approaches in their research applications that do not require the use of whole animals, use alternative species such as nonmammals or invertebrates, reduce the number of animals required, and incorporate refinements to procedures that will result in the elimination or further minimization of pain and distress to animals.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), which is available in the office of sponsored research at most academic and research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594/-7248. To identify the application as a response to this program announcement, check "YES" in Item 2a on the face page of the application and enter the program announcement title and number. Applications will be accepted in accordance with the usual receipt dates for new research grant applications; i.e., February 1, June 1, and October 1. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review. Applications will be received by the NIH Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or principal investigator should be included with the application.

The original and five copies of the application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

The review criteria customarily employed by the NIH for regular research grant applications will prevail. Following the initial scientific review, the applications will be evaluated by the appropriate National Advisory Council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that ICD. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review; availability of funds; program balance among research areas of the announcement.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

George S. Malindzak, Jr., Ph.D.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
104 T.W. Alexander Drive
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-3289
FAX: (919) 541-2843

Marshall Plaut M.D.
Asthma and Allergy Branch
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4A23
Bethesda, MD 20892
Telephone: (301) 496-8973
FAX: (301) 402-2571

Suzanne S. Hurd, Ph.D.
Division of Lung Diseases
National Heart, Lung and Blood Institute
Westwood Building, Room 6416
Bethesda, MD 20892
Telephone: (301) 594-7430
FAX: (301) 594-7408

Direct inquiries regarding fiscal matters to:

David L. Mineo
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

Jeffrey Carow
Immunology Grants Management Section
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B29
Bethesda, MD 20892
Telephone: (301) 496-7075

Mr. Raymond L. Zimmerman
Division of Extramural Affairs
National Heart, Lung and Blood Institute
Westwood Building, Room 4A11C
Bethesda, MD 20892
Telephone: (301) 594-7430

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Numbers 93.112, Characterization of Environmental Health Hazards; 93.113, Biological Response to Environmental Health Hazards; and 93.855, Allergy, Immunology and Transplantation Research. Awards are made under the authority of Section 487, Public Health Service Act as amended (42 USC 288) and administered under PHS Grants Policies and Title 42 of the Code of Federal Regulations, Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

DISSERTATION RESEARCH GRANTS IN: CHILD AND ADOLESCENT DEVELOPMENTAL PSYCHOPATHOLOGY; HIV/AIDS RESEARCH; MENTAL HEALTH SERVICES RESEARCH

NIH GUIDE, Volume 23, Number 16, April 29, 1994

PAR AVAILABLE: PAR-94-063

P.T. 34; K.W. 0730057, 0710105, 0715008

National Institute of Mental Health

Application Receipt Dates: August 10, 1994, December 13, 1994, and April 11, 1995

THIS IS A NOTICE OF AVAILABILITY OF A PROGRAM ANNOUNCEMENT (PA); IT IS ONLY AN ABSTRACT OF THE PA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE PA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE PA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The purpose of this program announcement is to stimulate and encourage doctoral candidates to carry out dissertation research in Child and Adolescent Developmental Psychopathology; HIV/AIDS Research; or Mental Health Services Research and to motivate a critical mass of candidates to make a commitment to research careers in one of these selected areas of importance to NIMH.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Dissertation Research Grants in: Child and Adolescent Developmental Psychopathology; HIV/AIDS Research; and Mental Health Services Research, is related to the priority area of mental health and mental disorders. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY

The applicant investigator applying for a dissertation research grant must be enrolled in an accredited doctoral degree program in the behavioral, biomedical, or social sciences and must be conducting or intending to conduct research in one of the three areas specified in this program announcement. Minority and women doctoral candidates and candidates with disabilities are especially encouraged to apply for these grants.

The applicant must be a registered doctoral candidate in resident or nonresident status. All requirements for the doctoral degree other than the dissertation must be completed by the time of the award. This information and the approval of the dissertation topic by a named committee must be verified in a letter of certification from the thesis chairperson and submitted with the grant application.

The applicant institution administering the grant on behalf of the proposed applicant must be domestic. Applications may be submitted by any public or private non-profit university, college, or professional school. The doctoral candidate must be a citizen or noncitizen national of the United States or hold a permanent residence visa.

MECHANISM OF SUPPORT

The mechanism of support is the National Institutes of Health (NIH) small grant (R03). Grants to support dissertation research will provide no more than \$25,000 in direct costs; they are awarded for 12 months, but may be extended without additional funds for up to 24 months. Awards will depend on the availability of funds.

RESEARCH OBJECTIVES

Research objectives in the area of Child and Adolescent Developmental Psychopathology include, but are not limited to, studies of a wide range of factors relevant to various risk or psychopathological conditions; processes underlying adaptive and maladaptive outcomes in populations at risk for psychopathology; and implications of developmental processes for effective interventions with children and adolescents.

Research objectives in the area of HIV/AIDS Research include, but are not limited to, studies of: brain, immune system, and neural aspects of HIV infection; the development of behavior change and prevention strategies to reduce the further spread of the epidemic; determinants of high-risk behaviors, of maintaining low-risk behaviors, and of the social contacts in which risk taking occurs; the measurement, course and treatment of HIV-related mental disorders; the problems of hard to reach and special populations at risk for, or with, HIV infection or AIDS (such as children, parents, the severely mentally ill, rural, and minority populations); and the impairment of access to, and delivery of, mental health services to persons affected by HIV.

Research objectives of Mental Health Services Research include, but are not limited to, studies examining the availability, quality, cost, structure, and effectiveness of mental health and related services; supply and use of mental health services, help-seeking and self-help behavior; disability assessment and rehabilitation services; effects of changes in the health care/mental health care system; impact of legislation and regulations on the provision of health care; and the effectiveness and outcomes of service delivery systems.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), available from university offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. The title and number of the program announcement must be typed in Section 2a on the face page of the application. Applications will be accepted for the receipt dates of August 10, 1994, December 13, 1994, and April 11, 1995.

Special Instructions

Special instructions included in the complete Program Announcement must be followed. A letter certifying the approval of the doctoral dissertation, identifying members of the dissertation committee, and addressing additional requirements must be submitted with the application. A transcript of the applicant's graduate school record and a scientific autobiography also should be included with the application.

The applicant must submit the original and five copies of the completed application, which includes a detailed narrative project description (not to exceed 10 pages) to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

These applications will be reviewed initially by non-Federal experts in the review group. Review of review will be conducted by senior NIMH staff members. Reviewers will take into account the applicant's stage of development and the importance of the dissertation project as a learning experience that is part of the applicant's graduate education. Detailed review criteria will be found in the complete PA.

AWARD CRITERIA

Final funding decisions are based on recommendations of the reviewers; the relevance of the project to child and/or adolescent developmental psychopathology, HIV/AIDS, or mental health services; program balance; and availability of appropriated funds.

INQUIRIES

Written and telephone requests for the program announcement and the opportunity to clarify any issues or questions from potential applicants are welcome. Inquiries regarding programmatic issues may be directed to:

Leonard Mitnick, Ph.D.
Office on AIDS
National Institute of Mental Health
5600 Fishers Lane, Room 10-75
Rockville, MD 20857
Telephone: (301) 443-6100
FAX: (301) 443-9719

Inquiries related to fiscal matters or grants management issues may be directed to:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-08
Rockville, MD 20857
Telephone: (301) 443-3065

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Awards are under the authorization of the Public Health Service Act, Title IV, Part A, Public Law 78-410, as amended, and administered under PHS grants policies and regulations 42 CFR 52 and 45 CFR 74. The program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ERRATUMBASIC OSTEOPOROSIS NEW EXPERIMENTAL STRATEGIES

NIH GUIDE, Volume 23, Number 16, April 29, 1994

RFA AVAILABLE: AR-94-005

P.T. 34; K.W. 0715031

National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute on Aging

Letter of Intent Receipt Date: June 28, 1994
Application Receipt Date: July 26, 1994

RFA AR-94-005, which was published in the NIH Guide for Grants and Contracts, Vol. 23, No. 13, April 1, 1994, contained an incorrect contact for the National Institute on Aging. The correct reference is:

Sherry Sherman, Ph.D.
Endocrine and Musculoskeletal Branch
National Institute on Aging
Gateway Building, Suite 3E 327
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-6761
FAX: (301) 402-1784

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5333 Westbard Avenue
Bethesda, MD 20816

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For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 17
May 6, 1994

RICHARD W MURRY

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81350E

929 WILD FOREST DRIVE
GAITHERSBURG MD 20879 3209

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THIS PUBLICATION IS AVAILABLE ELECTRONICALLY TO INSTITUTIONS VIA BITNET OR INTERNET AND IS ALSO ON THE NIH GOPHER. ALTERNATIVE ACCESS IS THROUGH THE NIH GRANT LINE USING A PERSONAL COMPUTER (DATA LINE 301/402-2221). CONTACT DR. JOHN JAMES AT 301/594-7270 FOR DETAILS.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

NOTICES

AVAILABILITY OF DRUG USE DATA

NIH GUIDE, Volume 23, Number 17, May 6, 1994

P.T. 34; K.W. 0404009, 0755018

National Institute on Drug Abuse

PURPOSE

In the October 29, 1993 (Vol. 22, No. 39) issue of the NIH Guide for Grants and Contracts, a new program announcement (PA-94-007) titled: "Survey Research on Drug Use and Associated Behaviors," was published. As an update to that program announcement, data from the 1985, 1988, 1990, and 1991 National Household Surveys on Drug Abuse are now available from the Substance Abuse and Mental Health Services Administration, Public Health Service. These data are public use files designed to be used for secondary data analysis.

INQUIRIES

Direct inquiries regarding access to these data files to:

Joseph Gfroerer or Janet Greenblatt
Office of Applied Studies
Substance Abuse and Mental Health Services Administration
Parklawn Building, Room 16C-06
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-7981

Direct inquiries regarding programmatic issues to:

Arthur Hughes or Andrea Kopstein
Division of Epidemiology and Prevention Branch
National Institute on Drug Abuse
Parklawn Building, Room 9A-53
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6637

AMERICAN TYPE CULTURE COLLECTION - U-937 CELL LINE

NIH GUIDE, Volume 23, Number 17, May 6, 1994

P.T. 34; K.W. 0780015

National Center for Research Resources

The National Center for Research Resources supports the American Type Culture Collection (ATCC), which is an international resource to provide scientists with a variety of biological material. This is a notification sent to all recipients of the cell line ATCC-CRL 1593 (U-937) from Freeze lot F-11205. A cellular cross contamination has been discovered and confirmed by PCR and cytogenetic analyses at the ATCC. The inappropriate cell line has not yet been identified, but is human and has a chromosomal mode of 67 plus other properties different from those of U-937. DNA and cell progeny from additional stocks of U-937 are currently under scrutiny. Results will be made public in due course.

The ATCC appreciates that this contamination will have caused considerable confusion plus wasted effort in recipients' laboratories and sincerely regrets the problem. The situation emphasizes the critical need for repeated testing of stocks of cells and organisms for purity. Upon request ATCC will provide replacements for all cultures of F-11205 with aliquots of a new lot of U-937 having authenticity confirmed.

INQUIRIES

Direct programmatic inquiries regarding this resource to:

Elaine Young, Ph.D.
ATCC Project Officer
National Center for Research Resources
Westwood Building, Room 854
Bethesda, MD 20892
Telephone: (301) 594-7906

Direct requests for updated information and replacement cultures to:

Robert Hay, Ph.D., Head
Cell Culture Department
American Type Culture Collection
12301 Parklawn Drive
Rockville, MD 20852-1776
Telephone: (301) 231-5529
FAX: (301) 770-1848

PREPARATION/DELIVERY OF HOMOGENEOUS CERAMIDETRIHEXOSIDASE

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFP AVAILABLE: NIH-NINDS-94-09

P.T. 34; K.W. 0780005, 0760013, 0760080

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, has a requirement to develop a method of producing ceramidetrihexosidase by recombinant means, isolating the enzyme, and supplying it in a form suitable for intravenous injection into patients with Fabry's disease. The enzyme preparation shall consist of a single (homogeneous) protein. The purified enzyme will catalyze the hydrolysis of a minimum of $2.0 \times 1,000,000$ nanomoles of 4-methylumbelliferyl alpha-D-galactopyranoside per milligram of protein per hour at 37 degrees. The enzyme will also catalyze the hydrolytic cleavage of 800,000 nanomoles of the terminal molecule of galactose from ceramidetrihexoside per milligram of protein per hour. The Contractor shall be required to deliver 650 milligrams of recombinant ceramidetrihexosidase according to the following schedule: 150 milligrams by the end of contract year 1; 200 milligrams by the end of contract year 2; and 300 milligrams by the end of contract year 3. At the time of proposal submission, the offeror's facilities must meet Food and Drug Administration (FDA) standards in accordance with draft Guidelines on the Preparation of Investigational New Drug Products (Human and Animal) (March 1991) under current good manufacturing practices and/or the technical requirements under the Statement of Work of the forthcoming Request for Proposals (RFP). It is anticipated that a single award will be made for an initial contract period of one year in March 1995, with two subsequent one-year option periods.

INQUIRIES

This is not an RFP. An RFP will be issued on or about May 10, 1994 and proposals will be due by COB June 30, 1994. To receive a copy of the RFP, submit a written request with two self-addressed mailing labels to:

Lynne M. Darby
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
ATTN: NIH-NINDS-94-09

All responsible sources will be considered by the agency.

SAFE AND EFFECTIVE STIMULATION OF NEURAL TISSUE

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFP AVAILABLE: NIH-NINDS-94-10

P.T. 34; K.W. 0745047, 0706000, 0706040, 0750005

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, is seeking a contract to develop neural stimulating microelectrodes and evaluate the effects of electrical stimulation on neural and surrounding tissue in non-human animals. Studies have established a safe level of intracortical stimulation with single penetrating microelectrodes, but essentially nothing is known about the safe limits for multiple, closely-spaced microelectrodes such as would be used in a visual prosthesis. Progress has been made on understanding the causes of tissue damage at the higher levels of stimulation. In order to minimize tissue damage, more information is needed on methods of preventing damage, the safety of new biomaterials, as well as better methods of physically stabilizing microelectrodes in neural tissue. The possibility of using multicontact integrated circuit microelectrodes with long shanks to access buried cortical tissue also needs to be investigated. Histopathological, neurochemical, and neurophysiological techniques must be applied to determine the effects of both acute and chronic activation of neural tissue. Electrodes to be used will include discrete wire intracortical microelectrodes as well as silicon microcircuit microelectrodes furnished by the Project Officer. Personnel with expertise in histological tissue examination and facilities are needed. It is anticipated that one award will be made for a period of three years in January 1995.

INQUIRIES

This is not a Request for Proposals (RFP). An RFP will be issued on or about April 26, 1994 with proposals due on June 27, 1994. All responsible sources will be considered by the agency. To receive a copy of the RFP, submit a written request along with two self-addressed mailing labels to:

Laurie A. Leonard
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
ATTN: NIH-NINDS-94-10

MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFP AVAILABLE: NIH-NINDS-94-11

P.T. 34; K.W. 0745047, 0706000, 0706040, 0715140, 0750005

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, is seeking a contract to develop and test a system for functional neuromuscular stimulation (FNS) consisting of implantable receiver-stimulators and transducers-telemeters and an easily donned extracorporeal transmitter. Multiple implantable microstimulators that selectively stimulate paralyzed muscles in a controlled fashion may permit an individual to use his or her own muscles as the motors to produce limb movement. Multiple implantable microtransducers that sense contact, grasp force, and limb position from either implanted transducers or intact sensory receptors may provide sensory feedback from an otherwise insensate limb. To produce a useful system, these sensory and motor prostheses are being developed together as standard and compatible building blocks of an integrated FNS system. Personnel with expertise in animal testing, telemetry, biomaterials, packaging, custom circuit design, and bioengineering are needed. It is anticipated that one award will be made in February 1995 for a period of three years.

INQUIRIES

This is not a Request for Proposals (RFP). An RFP will be issued on or about April 26, 1994 with proposals due on June 27, 1994. All responsible sources will be considered by the agency. To receive a copy of the RFP, submit a written request, along with two self-addressed mailing labels to:

Laurie A. Leonard
Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
ATTN: NIH-NINDS-94-11

ANGIOGENESIS IN BREAST CANCER

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFA AVAILABLE: HL-94-014

P.T. 34; K.W. 0715036, 0715040

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: August 1, 1994
Application Receipt Date: September 13, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES", BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Heart and Vascular Diseases invites research grant applications for up to four years of support for research into breast cancer angiogenesis. The objective of this RFA is to encourage vascular biologists to apply their knowledge and skills to elucidate the mechanisms whereby breast tumor cells stimulate angiogenesis and control the structure and function of the tumor blood vessels. The ultimate goal is to identify strategies that offer possibilities for treating breast cancer by inhibiting the vascularization of tumors.

Although recent progress has led to the accumulation of much knowledge on the subject of angiogenesis, that information has yet to be synthesized in a manner that would allow the rational consideration of new treatment modalities. Moreover, knowledge has been developed by study of normal tissues, bone marrow, and many different tumors. The purpose of this initiative is to focus on breast tumors and the specific mechanisms of stimulation and inhibition of angiogenesis in those tissues. The powerful tools of molecular biology and immunology combined with animal models and possibly cell lines provide the means to increase knowledge in this area.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Angiogenesis in Breast Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

Trans-NIH Breast Cancer Collaborative Effort

This RFA is part of the activities to be initiated by the National Institutes of Health (NIH) to advance knowledge regarding the etiology, treatment, and prevention of breast cancer.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to this RFA may not exceed four years. This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with other investigator-initiated applications and be reviewed according to the customary peer review procedures.

FUNDS AVAILABLE

Approximately \$1.5 million in total costs will be provided for the first year of support for the entire program. It is anticipated that no more than eight grants will be awarded under this program. This level of support is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plan of the NHLBI, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Administrative adjustments in project period and/or amount of support may be required at the time of the award.

RESEARCH OBJECTIVES

Background

The average U.S. mortality rate for breast cancer is 27.5 per hundred thousand women. Approximately 46,000 women died of breast cancer in 1993. Thus, despite vigorous efforts to diagnose, treat and prevent this disease, it remains a leading cause of death among women. In order to develop new approaches to the treatment of this disease, further knowledge is needed of the basic biology underlying the etiology and progression of the disease. The orientation of this initiative is on the mechanisms whereby cancer tumor cells promote angiogenesis as a means of providing nutrients to the tumor cells and a conduit for escape of tumor cells into the circulation. Recent studies have shown that vascularization is significantly higher in node-positive breast tumors than it is in node-negative tumors, and that a high degree of vascularization is generally associated with a poorer prognosis. This finding has led to the conclusion that inhibition of angiogenesis offers a possible therapeutic modality for a subset of patients. Circulation in a tumor has both favorable and detrimental aspects. The existence of blood vessels provides for the delivery of antitumor therapeutic agents at the same time it provides an escape route for metastases.

A fundamental question that remains unanswered is the process whereby angiogenesis is initiated in an avascular tumor. Tumors can remain avascular and survive by growth at the periphery and necrosis at the center for several years before angiogenesis begins. On the other hand, some breast tumors metastasize before they are clinically detectable, and it is not clear whether angiogenesis is a very early event in these cases. Investigations into the process by which tumor cells may switch to the angiogenic phenotype include the following mechanisms: (1) basic fibroblast growth factor (bFGF) normally confined within cells or bound in the extracellular matrix is reported to be released when tumor cells become angiogenic, and (2) angiogenic inhibitors secreted by cells decrease with the onset of angiogenesis presumably due to the loss of a tumor suppressor. The mechanism may be tumor specific. It is important to know whether these or other mechanisms stimulate angiogenesis in breast cancer.

Also involved in the angiogenic process are circulating cells recruited to tumor sites, i.e., neutrophils, monocytes, macrophages, lymphocytes, eosinophils, basophils, and mast cells. Their specific roles are only partially understood. Of these cells, only macrophages appear to have the ability to stimulate angiogenesis alone. Whether mast cells play a role in the initiation of angiogenesis, remains to be elucidated. Heparin released from mast cells is thought to have a role in potentiating angiogenesis, but is not thought to be able to act alone. Moreover, in other circumstances, heparin appears to be antiangiogenic. Lastly, although the lymphatic system is known to play a critical role in the process of metastasis, it remains unclear whether there are lymphatics within the breast tumor and how the tumor vasculature relates to the host lymphatic system.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 1, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel, and the number and title of this RFA. A letter of intent is not required, is not binding, and does not enter into the review of subsequent applications. The information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the selection of reviewers. The letter of intent is to be sent to:

C. James Scheirer, Ph.D.
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557
Bethesda, MD 20892
Telephone: (301) 594-7452
FAX: (301) 402-1660

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from the NIH Project Scientist listed under INQUIRIES.

Applications must be received by September 13, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NHLBI staff will contact the applicant to determine whether to return the application or submit it for review in competition with unsolicited applications at the next review cycle.

Applications may be triaged by an NHLBI peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NHLBI. The second level of review will be provided by the National Heart, Lung, Blood Advisory Council.

The review criteria for this RFA are: the novelty, originality and feasibility of the approach and the adequacy of the experimental design; the competence of the principal investigator and collaborators to accomplish the proposed research, and the commitment and time they will devote to the project; the suitability of the facilities to perform the proposed research, including laboratories, instrumentation and data management systems; the appropriateness of the requested budget and duration for the proposed research; adequate plans for interaction and communication of information and concepts among investigators involved in collaborative studies.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Constance Weinstein
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C06
Bethesda, MD 20892
Telephone: (301) 496-1081
FAX: (301) 480-6282

Inquiries regarding fiscal and administrative matters may be directed to:

Mr. William Darby
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11
Bethesda, MD 20892
Telephone: (301) 594-7458
FAX: (301) 594-7492

AUTHORITY AND REGULATIONS

This project is described in the Catalog of Federal Domestic Assistance No. 93.837. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR 74. This project is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFA AVAILABLE: CA-94-017

P.T. 34; K.W. 0715035, 0785055, 0745027, 0795003

National Cancer Institute

Letter of Intent Receipt Date: June 15, 1994

Application Receipt Date: September 23, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI), invites research grant applications from investigators new to this area of research, who are in the early stages of their career, to conduct studies translating phase I (hypothesis development) and II (methods development) basic, epidemiological, and clinical research into new approaches for the prevention and control of cancer.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Translational Investigator Grants for Cancer Prevention and Control, is related to the priority area of cancer. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, non-profit and for-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of state or local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged.

The Principal Investigator (PI) must have a doctoral degree and be working independently, but at the beginning stages of his or her research career in the areas of translational prevention and control research.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed four years. The total direct cost for the four year period may not exceed \$500,000. The direct cost in any budget period may not exceed \$150,000. The anticipated award date is July 1, 1995.

Awards and level of support depend on receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose.

This RFA is a one-time solicitation for FY 95.

FUNDS AVAILABLE

Approximately \$1.5 million, per year, in total costs for four years will be committed to fund applications submitted in response to this RFA. It is anticipated that eight awards will be made.

RESEARCH OBJECTIVES

There is concern about the declining number of investigators entering and remaining in academic research related to cancer prevention and control. These investigators are a critical component in translating phase I and phase II prevention and control research from epidemiological studies, the laboratory, and the clinic to broader venues such as physician practices, Health Maintenance Organizations (HMOs), and communities. This translational investigator is considered distinct from the investigator who has a Ph.D. or equivalent training and concentrates on basic or epidemiological research, or the M.D. clinician who participates in cancer research by entering patients on clinical trials.

The objective of this initiative is to encourage qualified cancer prevention and control investigators to develop grant applications to conduct interventions and trials that translate phase I and II research into new means of preventing particular cancers or improving survival from cancers. Grant applications must include trials and interventions involving human subjects and be designed to ultimately reduce the incidence of particular cancers or improve cancer survival.

It is expected that at least 30 percent effort will be committed to the research project by the Principal Investigator.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by June 15, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NCI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Helen Meissner at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Method of Applying

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), which are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Mrs. Toby Friedberg
Referral Office
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 636
Bethesda, MD 20892

Applications must be received by September 23, 1994. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG and responsiveness by the NCI. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle.

Applications may receive a preliminary scientific peer review (triage) by an NCI peer review group for relative competitiveness. The NIH will withdraw from further consideration those applications judged to be noncompetitive for award and will notify the Principal Investigator and institutional office. Those applications judged to be competitive will undergo further scientific merit review in accordance with the review criteria listed in the RFA, by an appropriate peer review group convened by the National Cancer Institute. The second level of review will be by the National Cancer Advisory Board.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA, inquiries regarding programmatic issues, and address the letter of intent to:

Helen Meissner, Sc.M.
Division of Cancer Prevention and Control
National Cancer Institute
Executive Plaza North, Room 330
Bethesda, MD 20892
Telephone: (301) 496-8520

Direct inquiries regarding fiscal matters to:

Robert E. Hawkins
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 213

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under HHS policies and grant regulations. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISMS OF AIDS PATHOGENESIS

NIH GUIDE, Volume 23, Number 17, May 6, 1994

RFA AVAILABLE: AI-94-018

P.T. 34; K.W. 0715008, 0765033, 0705048

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: September 16, 1994

Application Receipt Date: November 16, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications from single institutions or consortia of institutions for research project grants focusing on a hypothesis for AIDS-related pathogenesis. This RFA specifically solicits applications for in vivo research of AIDS-related pathogenesis utilizing state-of-the-art methods and approaches. In vivo research includes studies of human clinical or epidemiologic cohorts, of animal models, or of appropriate specimens from humans or animals. Research supported by this RFA is limited to one or more of three scientific areas: (1) non-human primate models of Human Immunodeficiency Virus (HIV) immunopathogenesis, (2) sexual/mucosal transmission of HIV or Simian Immunodeficiency Virus (SIV), and (3) host factors that modulate HIV or SIV infection or disease. Although the research necessary to test a proposed pathogenesis hypothesis may be possible within a single laboratory, the NIAID anticipates that highly competitive applications may require separate components at the same or different institutions specializing in different scientific disciplines (e.g., molecular biology, biochemistry, cellular biology, cellular immunology, genetics, and biophysics).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Mechanisms of AIDS Pathogenesis, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local government, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

Awards made under this RFA will use the National Institutes of Health (NIH) individual research project grant (R01) award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted by domestic institutions may not exceed four years; the total project period for applications submitted by foreign institutions may not exceed three years. Applicants are encouraged to coordinate, through the use of consortium arrangements or subcontracts, integrated approaches with individuals or institutions having relevant reagents and expertise in their use, demonstrated ability in a particular area of relevant research, or access to relevant animal or patient populations.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards made under this RFA will be \$6 million. Foreign applications or components that may be funded under this RFA are not eligible for indirect costs. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of the awards will vary also. The NIAID anticipates 8 to 16 awards under this RFA. This RFA may be a one-time solicitation.

It is the intent of the NIAID to fund applications in each of the three scientific areas described above. The number of awards and level of support depend upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIAID, awards pursuant to this RFA are contingent upon the availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress and availability of funds.

RESEARCH OBJECTIVES

Research grant applications responsive to this RFA should provide innovative, focused approaches to test a hypothesis of HIV pathogenesis in non-human primate models, HIV or SIV sexual/mucosal transmission, or host factors that modulate HIV or SIV infection or disease. The NIAID anticipates that investigators will propose studies testing hypotheses using state-of-the-art methods on specimens from human and/or animal models. Although the research necessary to test a proposed pathogenesis hypothesis may be possible within a single laboratory, the NIAID anticipates that highly competitive applications may require separate components at the same or different institutions specializing in different scientific disciplines.

Descriptive, non-hypothesis driven, research is not within the scope of this RFA. Drug and vaccine trials in animal models, and clinical trials and recruitment or retention of cohorts will not be supported under this RFA.

SPECIAL REQUIREMENTS

Principal Investigators and other key members will be requested to attend an annual NIAID AIDS Pathogenesis Meeting to include grantees of the Mechanisms of AIDS Pathogenesis RFA, to be held each year at a site designated by NIAID (Bethesda, Maryland is anticipated). To best utilize limited funds, applicants are encouraged NOT to include funds for travel to other scientific meetings in their budgets.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 16, 1994, a letter of intent that includes the number and title of the RFA; a descriptive title of the proposed research; names, addresses, telephone numbers, and EMAIL addresses (if available) of the Principal Investigator, component leaders and other key personnel; and the name of the primary institution and component institutions (if different). Although a letter of intent is not required, is not binding, and does not enter into the review of the application, the information that it contains is helpful in planning for the review of expected applications.

The letter of intent is to be addressed to Dr. Dianne Tingley at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91), the standard application form for research grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/594-7248. Applicants must adhere to the format and requirements specified in the PHS 398 application kit.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) staff for completeness and by NIAID staff to determine administrative and programmatic responsiveness to this RFA. Those judged to be incomplete or nonresponsive will be returned to the applicant without review. Those considered complete and responsive may be subjected to a triage review by an NIAID peer review group to determine their scientific competitiveness relative to the other applications submitted in response to this RFA. The NIAID will withdraw from competition those applications judged by the triage peer review group to be noncompetitive for award and will notify the Principal Investigator and the institutional business official. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by a review committee convened by the Division of Extramural Activities, NIAID. Peer reviewers will base their comments and recommendations solely on the written application, which must be complete and prepared according to the RFA guidelines. A second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council. Applicants are strongly encouraged to discuss research plans and organizational structure with DAIDS program staff in the early stages of preparation of the application. The factors considered in evaluating the scientific merit of each application are included in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome. Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Gregory Milman
Division of AIDS
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2B35
Bethesda, MD 20892
Telephone: (301) 496-8378
FAX: (301) 480-5703

Address the letter of intent and direct any questions regarding review procedures to:

Dr. Dianne Tingley
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C16
Bethesda, MD 20892
Telephone: (301) 496-0818
FAX: (301) 402-2638

Direct inquiries regarding fiscal matters to:

Ms. Jane Unsworth
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B22
Bethesda, MD 20892
Telephone: (301) 496-7075
FAX: (301) 480-3780

The above individuals may also be addressed by EMAIL to:

MAPS@EXEC.NIAID.PC.NIAID.NIH.GOV

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergy and Transplantation Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

SHORT-TERM RESEARCH TRAINING FOR MINORITY STUDENTS

NIH GUIDE, Volume 23, Number 17, May 6, 1994

PA NUMBER: PAR-94-064

P.T. 44, FF; K.W. 0720005, 0725000

National Institute of Environmental Health Sciences

Application Receipt Dates: July 15, 1994 and May 10 each subsequent year.

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) announces a program to support short-term biomedical research training experiences for minority undergraduate students in areas related to defining and understanding the action of environmental agents on human health. The purpose of the award is to encourage institutions with a significant environmental health sciences research and training program to provide opportunities for underrepresented minority students who have expressed an interest in a career in biomedical research. The intent is to interest highly motivated and qualified minorities at the undergraduate level in developing both their interests and scientific capacity to pursue a professional career in biomedical research relevant to the environmental health sciences.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Short-Term Research Training for Minority Students, is related to the priority area of environmental health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Awards under this program will be made to domestic institutions or organizations, including minority institutions, engaged in health related research in areas of environmental health sciences. These grants will support full-time, short-term research training experiences of one to three months duration for underrepresented minority undergraduate students. Trainees appointed to the program need not be from the grantee institution, but may include a number of minority students from other institutions, schools, colleges or universities. Trainees may be appointed for up to three separate short-term training periods. However, in no circumstance may a training period exceed three months in any year. The grantee institution will be responsible for the selection and appointment of trainees.

In order to facilitate the training of minority students, the NIEHS has determined that this research training could be facilitated as a part of an ongoing research training program. Therefore, applications from existing NIEHS Institutional Training Grant (T32) programs are strongly encouraged. Also, only institutions with a significant, peer-reviewed NIEHS research grant are eligible to apply.

For the purpose of this program, underrepresented minority students are defined as individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. Awards will be limited to United States citizens or to individuals who have been lawfully admitted for permanent residence (i.e., in possession of an Alien Registration Receipt Card) at the time of application. In awarding grants, the NIEHS will give priority to programs involving Black, Hispanic, Native American, and Pacific Islander or other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research nationally.

Trainees should have successfully completed at least one undergraduate year at an accredited school or university prior to participating in the program. In addition, the student should be interested in a career in biomedical research in environmental health sciences. These grants are intended to introduce, foster, and develop the interest and capability of students in environmental health sciences research that would not otherwise be available through their regular course of studies. This program is intended to increase the number of qualified minorities for professional careers in environmental health sciences research by increasing the number of qualified applicants for graduate training programs.

MECHANISM OF SUPPORT

The mechanism of support is the institutional National Research Service Award for Short-Term Training of Students (T35). Institutions may request up to five years of support for short-term training programs for at least three and not more than six trainees per year. As indicated above, applications from existing NIEHS T32 awardees are strongly encouraged. The stipend level for trainees is \$834 per month. Stipends may be supplemented from non-Federal funds. Training-related expenses up to \$250 per month, per trainee, may be requested. In addition, up to \$500 per trainee may be requested to cover domestic travel to and from the training site, and up to \$400 per month, per trainee may be requested to cover the cost of housing and subsistence at the training site. Trainee tuition and fees, where necessary to the research training, must be covered by the training-related expenses. Indirect costs will be awarded based on eight percent of total direct costs, exclusive of tuition and fees.

Supplementation of stipends when provided must not require an obligation from the fellow. Under no circumstances may Federal grant funds be used for supplementation unless specifically authorized under the terms of the program from which the funds are derived.

RESEARCH OBJECTIVES

In the NIH Revitalization Act of 1993, the NIH was encouraged to increase the number of underrepresented minorities participating in biomedical and behavioral research. However, an analysis of the NIEHS training pool revealed that less than five percent of these individuals were underrepresented minorities. Less than one percent of the principal investigators of NIEHS research grants are underrepresented minorities. In addition, the number of underrepresented minority applicants for research grants and training positions was very low. This program will establish a mechanism for universities and other eligible institutions that are involved in environmental health sciences research and training to identify and train qualified underrepresented minorities earlier in their academic careers. The intent of this program announcement is to significantly improve the number and quality of students interested in research careers in environmental health sciences.

The Short-Term Research Training for Minority Students Program is designed to offer short-term training grant awards in environmental health sciences research to eligible institutions to enable qualified undergraduate students to become better prepared for a career in environmental health sciences research. It is expected to attract students in the developmental stages, to increase their awareness of environmental health sciences research, to improve their scientific skills and to acquaint them with career opportunities in research. It is expected that this program will increase in a direct and measurable way, the number and success of underrepresented minority students attracted to NIEHS training grants.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available in the offices of sponsored research at most academic and research institutions and from the Grants Information Office, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Additional information and guidelines for the program are available from the NIEHS, and can be obtained by contacting Dr. Michael Galvin at the address listed under INQUIRIES.

Except for the first year, which has a receipt date of July 10, there will be a single receipt date of May 10, each year. If an application is received after that date, it will be returned to the applicant.

To identify the application as a response to this program announcement, check "YES" in Item 2a on the face page of the application and enter the program announcement title, "SHORT-TERM RESEARCH TRAINING FOR MINORITY STUDENTS," and program announcement number, PAR-94-064.

A signed, typewritten original of the application, including the checklist, and five signed photocopies of the application must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications that do not meet the guidelines, including applications without a significant, peer-reviewed NIEHS research grant base, will be returned without review. Applications will be reviewed for scientific and technical merit by the Environmental Health Sciences Review Committee in accordance with the standard NIH peer review procedures for training grants.

Factors that will be used in the review to evaluate applications are:

- o evidence of an organized program for training students in environmental health sciences topics.
- o the availability of opportunities for students to participate in a research environment.
- o access to an appropriate student population.
- o institutional facilities and commitment such as housing, tutors, faculty time or other substantive commitments by the institution.
- o criteria for selecting students.

Following the initial review of scientific and training merit, the applications will receive a second-level review by the National Advisory Environmental Health Sciences Council.

AWARD CRITERIA

Applications will compete for available funds with all other training applications recommended for further consideration that have been assigned to the NIEHS. The following will be considered in making funding decisions.

- o Quality of the proposed training program, as determined by initial review.
- o Commitment of the institution to the program.
- o Availability of funds.
- o Program balance among the training areas supported by the NIEHS.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Michael Galvin, Jr.
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-02
Research Triangle Park, NC 27709
Telephone: (919) 541-7825
FAX: (919) 541-2843

Direct inquiries regarding fiscal matters to:

Ms. Jacqueline M. Russell
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, Building 2
Research Triangle Park, NC 27709
Telephone: (919) 541-7628
FAX: (919) 541-2860

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.894, Resource and Manpower Development in the Environmental Health Sciences. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 43 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
Bethesda, MD 20816***

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Building 31, Bethesda, Maryland 20892

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 23, No. 18
May 13, 1994

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This publication is available electronically to institutions via BITNET or INTERNET and is also on the NIH GOPHER. Alternative access is through the NIH Grant Line using a personal computer (data line 301/402-2221). Contact Dr. John James at 301/594-7270 for details.

THE PUBLIC HEALTH SERVICE (PHS) STRONGLY ENCOURAGES ALL GRANT RECIPIENTS TO PROVIDE A SMOKE-FREE WORKPLACE AND PROMOTE THE NON-USE OF ALL TOBACCO PRODUCTS. THIS IS CONSISTENT WITH THE PHS MISSION TO PROTECT AND ADVANCE THE PHYSICAL AND MENTAL HEALTH OF THE AMERICAN PEOPLE.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

INTERVENTIONS TO IMPROVE ASTHMA MANAGEMENT AND PREVENTION AT SCHOOL

NIH GUIDE, Volume 23, Number 18, May 13, 1994

BAA AVAILABLE: NHLBI-HR-94-15

P.T. 34; K.W. 0715013, 0745027

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) plans to use a Broad Agency Announcement (BAA) research and development contract program to develop and evaluate innovative programs to assure optimal asthma management and prevention at school. Program objectives include: identify cost-effective measures to increase identification and appropriate referral of children with uncontrolled asthma; reduce exposure to known allergens and irritants; increase participation of students with asthma in all school activities, including physical education and sports; improve support to the students for following their asthma management plans, especially assuring appropriate access to medications; and improve communication between the school and home. NHLBI hopes to make four awards. Offerors other than U.S. organizations will not be considered.

INQUIRIES

This is an announcement for Broad Agency Announcement (BAA). The BAA will be available on or about 20 April, 1994, with proposals due on or about 15 July, 1994. Written requests for the BAA must include three self-addressed mailing labels and cite BAA NHLBI-HR-94-15.

Requests for copies of the BAA are to be directed to:

Mr. Craig Miron
Contracts Operations Branch
National Heart, Lung and Blood Institute
7550 Wisconsin Avenue, Room 200
Bethesda, MD 20892

CLINICAL TRIAL OF MANAGEMENT STRATEGIES OF ATRIAL FIBRILLATION IN AN ELDERLY POPULATION

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFP AVAILABLE: NHLBI-HC-94-22

P.T. 34; K.W. 0715040, 0755015

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute is soliciting proposals for a clinical trial center to study two different strategies for the management of atrial fibrillation. The contractor will enroll approximately 5,300 patients to be randomized to one of the two management strategies. The first strategy will administer arrhythmia drugs to maintain normal sinus rhythm and the second group will be given a different group of drugs and/or catheter ablation for heart rate control only. The anticipated period of performance is seven years beginning on or about April 1, 1995. The Request for Proposal (RFP) NHLBI-HC-94-22 will be released on or about May 10, 1994 with proposals due on August 1, 1994. One award is anticipated from this RFP.

INQUIRIES

All requests must be in writing, cite RFP NHLBI-HC-94-22, and be addressed to:

Ms. Lisa O'Neill
Contracting Officer
ECA Contract Section
National Heart, Lung, and Blood Institute
7550 Wisconsin Avenue, Room 200
Bethesda, MD 20892

PROGRAM OF HEARING AID DEVICE DEVELOPMENT

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFP AVAILABLE: NIH-DC-94-02

P.T. 34; K.W. 0740030, 0706000

National Institutes on Deafness and Other Communication Disorders

The National Institute on Deafness and Other Communication Disorders, National Institutes of Health, has a requirement to design, develop, and evaluate in laboratory-based and field-trial studies, innovative speech processing strategies for hearing aids. The focus will be on new and creative approaches; although it may include the evaluation of recently developed strategies using existing technologies such as multiple microphone arrays, automatic signal processing technologies (e.g., fixed-frequency or level-dependent frequency response, compression amplification), and programmable hearing aids employing digital processing. Wearable speech processors will be developed for use in field trials. A four-year cost-reimbursement type contract is anticipated. The solicitation is scheduled to be issued on or about May

16, 1994. Proposals will be due 45 days after the date of issuance of the solicitation. All responsible sources may submit a proposal that will be considered by the Government.

INQUIRIES

Copies of the solicitation may be obtained by sending a written request to:

John P. DeCenzo
Research Contracts Branch, DCG/OD
National Institutes of Health
Building 31, Room 1B44
Bethesda, MD 20892
Telephone: (301) 496-4487

UNINTENDED PREGNANCY IN THE UNITED STATES

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: HD-94-022

P.T. 34; K.W. 0775020, 0404000, 0417000

National Institute of Child Health and Human Development

Application Receipt Date: August 19, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

APPLICATIONS IN RESPONSE TO THIS RFA WILL BE ASKED TO USE A MODIFIED (ABBREVIATED) GRANT APPLICATION FORMAT; SPECIFIC INSTRUCTIONS FOR COMPLETING THE APPLICATION ARE IN THE APPLICATION PROCEDURES BELOW.

PURPOSE

The Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD) invites scientists to submit grant applications for the support of research on the definition of, the measurement of and the determinants of intended VS unintended pregnancies and births in the contemporary U.S. Research on various aspects of contraceptive use and non-use is an important part of the Demographic and Behavioral Sciences Branch's program, within the Center for Population Research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Unintended Pregnancy in the U.S., is related to the priority areas of family and child health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-004734-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Applications from minorities, women and disabled persons are encouraged. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards.

MECHANISM OF SUPPORT

Applications in response to this RFA will be funded through individual research project grants (R01) and FIRST (R29) awards. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed five years. This RFA is for a single competition with the application receipt date of August 19, 1994. Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also. For R29 applications, the budgetary conventions governing FIRST awards will apply.

FUNDS AVAILABLE

The NICHD has set aside \$1,000,000 direct costs for the first year of support for the program. It is anticipated that four to six awards will be made depending on the nature and scope of the projects. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NICHD, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This RFA invites applications to conduct research on the meaning, measurement, and determinants of unintended pregnancy and birth in the contemporary United States. Two sets of research questions are at issue and applications may address aspects of either or both. First, the RFA seeks to provide a richer understanding of the meaning of unintended

pregnancy, as conventionally defined, as well as to build a scientific base for improved measures that may be used in demographic surveys. Second, the RFA seeks to improve and extend research on the determinants of unintended pregnancy and birth at the cultural, societal, couple, and individual levels.

Sociological, psychological, social-structural, and contextual approaches are welcomed. Qualitative as well as quantitative methodologies would be appropriate.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the NIH guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research. See the RFA for details.

APPLICATION PROCEDURES

Applications are to be submitted on form PHS 398 (rev. 9/91) that is available in most institutional offices of sponsored research and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. FIRST (R29) award applications must include at least three sealed letters of reference attached to the face page of the original application. FIRST (R29) award applications submitted without the required number of reference letters will be considered incomplete and will be returned without review. Applications must be identified by checking the "YES" box in Item 2a on the face page of the application and by typing "RFA HD-94-022." The RFA label in form PHS 398 must be affixed to the bottom of the face page of the original application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. Applications must be received by August 19, 1994. Late applications will not be accepted. The signed original and three copies of the applications must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Additional applications procedures are described in the RFA.

REVIEW CONSIDERATIONS

The applications will be reviewed for scientific merit by an initial review group convened solely for this purpose by the Division of Scientific Review, NICHD and the NICHD Advisory Council for program relevance and policy issues before awards for meritorious applications are made.

AWARD CRITERIA

The anticipated date of award is March 1995. Scientific merit and technical proficiency, as described in the application, will be the predominant criteria for determining funding.

INQUIRIES

Written and telephone requests for the RFA and inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Susan F. Newcomer, Ph.D.
Demographic and Behavioral Science Branch
National Institute of Child Health and Human Development
Building 61E, Room 8B13
Bethesda MD 20892
Telephone: (301) 496-1174
FAX: (301) 496-0962
Electronic mail: NewcomeS@HD01.NICHD.NIH.GOV

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
Building 6100, Room 8A17
Bethesda, MD 20892
Telephone: (301) 496-5481
FAX: (301) 402-0915

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864 (Population Research). Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations, 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

TUBERCULOSIS ACADEMIC AWARD

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: HL-94-016

P.T. 34; K.W. 0715165, 0502024, 0403004, 0795003

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: July 13, 1994

Application Receipt Date: September 14, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED BELOW IN "INQUIRIES." FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The primary objective of this RFA is to stimulate the development and/or improvement of the quality of medical curricula, physician/patient/and community education, and clinical practice for the prevention, management, and control of Mycobacterial tuberculosis (TB) in the United States.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Tuberculosis Academic Award, is related to the priority areas of immunization and infectious diseases, and HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Institutions

Applications may be submitted by domestic universities or schools of medicine.

In this competition, there is an interest in a diversity of types of applications. These include, but are not limited to, applications from any of the following: established researchers and/or faculty specializing in the field of tuberculosis, minority faculty members interested in medical education, minority medical institutions, institutions serving a high proportion of minority medical students or minority patients or institutions having other tuberculosis research projects to which this award would be complementary.

Candidates

A candidate for an award must:

- o be an established physician and a medical faculty member in an accredited school of medicine or osteopathy in the United States, its territories or possessions;
- o have the unqualified support of the Dean and the educational leadership at the institution and demonstrate knowledge and commitment to medical education for medical students, physicians, patients, and the public;
- o have sufficient clinical training, and experience in the control of TB to develop and implement a high quality curriculum in TB encompassing current knowledge and methods applicable to the control of tuberculosis in individuals of all ages and to provide leadership in applied research in control of TB;
- o be a citizen or non-citizen national of the United States or have been lawfully admitted to the United States for permanent residence at the time of application; and
- o commit at least 30 percent effort for a five year period.

Individuals who have held another NIH career development award (K series) are eligible to apply for the Tuberculosis Academic Award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA is part of the Academic Award Program (K07) of the National Heart, Lung, and Blood Institute. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period may not exceed five years and is non-renewable. It is anticipated that support for this program will begin April 1, 1995. (Applicants may request a July 1, 1995 start date.)

FUNDS AVAILABLE

The estimated funds (total costs) for fiscal year 1995 will be \$300,000. It is anticipated that three to four grants will be awarded each year for five years under this program. The specific number, however, will depend upon the merit and scope of the applications received and the availability of funds. A maximum of \$50,000 for the salary of the awardee, plus applicable fringe benefits, a maximum of \$20,000 for technical support, and indirect costs not to exceed eight percent may be requested for each year.

RESEARCH OBJECTIVES

The objectives of the Tuberculosis Academic Award are to:

- o encourage the development of high quality curricula in schools of medicine that will significantly increase the opportunities for students, house staff, and others, including practicing physicians, to learn the principles and practice of preventing, managing, and controlling TB;
- o develop and implement interdepartmental programs with common goals and standardized diagnostic and therapeutic approaches;
- o promote communication among primary care and other specialists to ensure appropriate control and treatment strategies;
- o encourage applied research in the control of TB;
- o promote the development of a faculty capable of providing appropriate instruction in diagnosis and management of TB, with special emphasis on minority faculty;
- o promote coordinated clinical approaches to the care of patients of various ages and ethnic groups who have TB;
- o provide for outreach programs from medical centers to health practitioners in the community to enhance optimal care, especially in areas of high TB morbidity;
- o contribute to updating the knowledge and skills of practicing physicians and other health care providers in the community;
- o enhance the awareness of health care providers of the unique ethnic, cultural, socioeconomic, and medical dimensions of TB;
- o coordinate and collaborate with other community organizations to control TB in areas with high incidence of TB;
- o facilitate an interchange of ideas and methods among awardees and institutions;
- o contribute to public health efforts to control TB in the United States; and
- o enhance the teaching of tuberculosis in minority medical schools and promote TB education in the communities served by these institutions.

Of particular interest are programs targeted to inner city populations and to rural areas that may be in need of education about tuberculosis and among physicians who are or who will be caring for medically underserved populations.

Since this is a medical education program, funds may be requested for technical support staff who have complementary expertise to the principal investigator. Such personnel may include medical educators, curricula specialists, program evaluators, or other specialists.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 13, 1994, a letter of intent that includes the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557A
Bethesda, MD 20892

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7428.

Applications must be received by September 14, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NHLBI staff will return the application to the applicant.

The initial review may include a preliminary evaluation to determine scientific merit relative to the other applications received in response to this program announcement (triage); the NIH will remove from further consideration applications judged to be noncompetitive and promptly notify the Principal Investigator and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by the usual peer review procedures, including, if deemed appropriate, an applicant interview in or near Bethesda at the applicant's expense. The initial review will be conducted by a Special Emphasis Panel, managed by the Division of Extramural Affairs, National Heart, Lung, and Blood Institute. The secondary review will be by the National Heart, Lung, and Blood Advisory Council.

Applications for this Tuberculosis Academic Award will be evaluated in terms of the criteria listed in the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Applicants are urged to contact the program administrator, listed below, as soon as they receive approval from their institution to apply for this award.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Joan M. Wolle, Ph.D., M.P.H.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 640
Bethesda, MD 20892
Telephone: (301) 594-7466

Direct inquiries regarding fiscal matters to:

Raymond L. Zimmerman
Grants Operations Branch
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
Bethesda, MD 20892
Telephone: (301) 594-7420

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.838. Grants are made under the authorization of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended by Public Law 99-158, 42 US 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to a review by a Health Systems Agency.

ASTHMA ACADEMIC AWARD

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: HL-94-017

P.T. 34; K.W. 0715013, 0502024, 0745027

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: July 13, 1994

Application Receipt Date: September 14, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACTS LISTED BELOW IN "INQUIRIES." FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The primary objective of this RFA is to stimulate the development and/or improvement of the quality of medical curricula, physician/patient/and community education, and clinical practice for the prevention, management, and control of asthma in the United States.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Asthma Academic Award, is related to the priority areas of diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Institutions

Applications may be submitted by domestic universities or schools of medicine.

In this competition, there is an interest in a diversity of types of applications. These include, but are not limited to, applications from any of the following: established researchers and/or faculty specializing in the field of asthma, minority faculty members interested in medical education, institutions serving a high proportion of minority medical students or minority patients, institutions having other asthma research projects to which this award would be complementary.

Candidates

A candidate for an award must:

- o be an established physician and medical faculty member in an accredited school of medicine or osteopathy in the United States, its territories or possessions;
- o have demonstrated knowledge and commitment to medical education for medical students, physicians, and patients;
- o have sufficient clinical training and experience in asthma to develop and implement a high quality curriculum in asthma encompassing current knowledge and methods applicable to the control of asthma in individuals of all ages and to provide leadership in applied research in control of asthma;
- o have the support of the Dean and educational leadership at the institution;
- o be a citizen or non-citizen national of the United States or have been lawfully admitted to the United States for permanent residence at the time of application; and
- o commit at least 30 percent effort for a period of five years.

Individuals who have held another NIH career development award (K series) are eligible to apply for the Asthma Academic Award. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA is part of the Academic Award Program (K07) of the National Heart, Lung, and Blood Institute (NHLBI). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period may not exceed five years and is non-renewable. It is anticipated that support for this program will begin April 1, 1995. (Applicants may request a July 1, 1995 start date.)

FUNDS AVAILABLE

The estimated funds (total costs) for fiscal year 1995 will be \$300,000. It is anticipated that three to four grants will be awarded under this program. The specific number, however, will depend upon the merit and scope of the applications received and the availability of funds. A maximum of \$50,000 for the salary of the awardee, plus applicable fringe benefits, a maximum of \$20,000 for technical support, and indirect costs not to exceed eight percent may be requested for each year.

RESEARCH OBJECTIVES

The objectives of the Asthma Academic Award are to:

- o encourage the development of high quality curricula in schools of medicine that will significantly increase the opportunities for students, house staff, and others, including practicing physicians, to learn the principles and practice of preventing, managing, and controlling asthma;
- o develop and implement interdepartmental programs with common goals and standardized diagnostic and therapeutic approaches;
- o promote communication among specialists in primary care, allergy, and obstetrics and gynecology to ensure appropriate treatment of pregnant women with asthma;
- o encourage applied research in the control of asthma;
- o promote the development of a faculty capable of providing appropriate diagnosis and management instruction in asthma, with special emphasis on minority faculty;
- o promote an institutional environment that facilitates an interchange of information and educational evaluation techniques about new diagnostic, therapeutic, and prevention measures in asthma in both children and adults;
- o promote coordinated clinical approaches to the care of patients of various ages and ethnic groups who have asthma, such as minorities, young children, and the elderly;
- o provide for outreach programs from medical centers to health practitioners in the community to enhance optimal care, especially in areas of high asthma morbidity, such as inner city minority communities;
- o facilitate an interchange of ideas among awardees and institutions;
- o evaluate the impact of the proposed program;

o contribute to the public health efforts to control asthma in the United States; and

o enhance the teaching of asthma in minority medical schools and promote community asthma education in the communities served by these institutions.

Of particular interest are programs targeted to inner city populations and to rural areas that may be in need of education about asthma and among physicians who are or who will be caring for medically underserved populations.

Since this is a medical education program, funds may be requested for technical support staff who have complementary expertise to the Principal Investigator. Such personnel may include medical educators, curricula specialists, program evaluators, or other specialists.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by July 13, 1994, a letter of intent that includes the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the RFA number and title in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NHLBI staff to estimate the potential review workload and to avoid conflict of interest in the review. The letter of intent is to be sent to:

Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 557A
Bethesda, MD 20892

APPLICATION PROCEDURES

Application are to be submitted on the grant application form PHS 398 (rev. 9/91). Application kits are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda MD 20892, telephone (301) 594-7428. Applications must be received by September 14, 1994.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, NHLBI staff will return the application to the applicant. The initial review may include a preliminary evaluation to determine scientific merit relative to the other applications received in response to this program announcement (triage); the NIH will remove from further consideration applications judged to be noncompetitive and promptly notify the Principal Investigator and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by the usual peer review procedures, including, if deemed appropriate, an applicant interview in or near Bethesda at the applicant's expense. The initial review will be conducted by a Special Emphasis Panel, managed by the Division of Extramural Affairs, National Heart, Lung, and Blood Institute. The secondary review will be by the National Heart, Lung, and Blood Advisory Council.

Applications for this Asthma Academic Award will be evaluated in terms of the criteria listed in the RFA.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Applicants are urged to contact the program administrator, listed below, as soon as they receive approval from their institution to apply for this award. Direct requests for the RFA and inquiries regarding programmatic issues to:

Joan M. Wolle, Ph.D., M.P.H.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 640
Bethesda, MD 20892
Telephone: (301) 594-7466

Direct inquiries regarding fiscal matters to:

Raymond L. Zimmerman
Grants Operations Branch
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
Bethesda, MD 20892
Telephone: (301) 594-7420

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.838. Grants are made under the authorization of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended by Public Law 99-158, 42 US 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CAR 52 and 45 CAR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to a review by a Health Systems Agency.

SILVIO O. CONTE DIGESTIVE DISEASES RESEARCH CORE CENTERS

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: DK-94-021

P.T. 04; K.W. 0715085, 0755030, 0765035, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: October 18, 1994

Application Receipt Date: November 15, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Silvio O. Conte Digestive Diseases Core Center grants. NIDDK anticipates the award of four competitive Silvio O. Conte Digestive Diseases Core Center Grants (P30s) in Fiscal Year 1996.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Silvio O. Conte Digestive Diseases Research Core Center grants, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic (not foreign) for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Minority individuals and women are encouraged to submit as principal investigators. Applicant institutions must have an adequate base of established programs of high quality in laboratory and/or clinical digestive diseases related research.

MECHANISM OF SUPPORT

Support of this program will be through the NIH grant in aid core center (P30) award. Responsibility for the planning, direction, and execution of the proposed center will be solely that of the applicant. This RFA is a one-time solicitation. The receipt of four competing continuation applications is anticipated. These applications will compete for four awards along with other applications received in response to this RFA. The total project period for each application submitted in response to the present RFA may not exceed five years. The earliest possible award dates will be December 1994 for three center grants and January 1995 for the other grant.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC program director or a Principal Investigator must be included with the application.

FUNDS AVAILABLE

For FY 1996, up to \$3,265,000 in total costs will be committed to fund applications submitted in response to this RFA. It is anticipated that four awards will be made with an average size of approximately \$750,000 per year, total costs; however, this funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Applicants must limit their requests to not more than \$700,000 direct costs for the initial budget period. Included in this \$700,000 are funds with a limit of \$100,000 for the pilot and feasibility program. Future budget period escalations should not exceed a four percent increase over the previous budget period. Although this program is provided for in the financial plans of the NIDDK, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The objective of the Digestive Diseases Core Centers is to bring together clinical and basic science investigators from relevant disciplines to enhance and extend the effectiveness of research related to digestive diseases and their complications. There must be an existing peer reviewed and funded program of excellence in this area. At least one half of the research must have a central theme or focus. Examples of a central theme or focus include, but are not restricted to, inflammatory bowel disease, peptic ulcer disease, liver disease, pancreatic disease, pediatric

gastrointestinal disease, GI hormones, GI motility, AIDS in gastrointestinal disease, or gene therapy. Core facilities which enhance productivity or in other ways benefit a group of investigators working in digestive diseases centers to accomplish the stated goals of the center will be supported. Two other activities may also be supported with center funding: (1) a pilot and feasibility grant program which may include temporary salary support for one Named New Investigator and (2) an enrichment program including for example, seminars, visiting scientists, consultants, and workshops. Close cooperation, communication, and collaboration among all involved personnel of all professional disciplines are ultimate objectives.

SPECIAL REQUIREMENTS

At least 50 percent of the already funded research base in a new application must be supported by NIDDK. In competing continuation applications the percent may be less than 50 percent due to, for example, a growing research base of investigators entering digestive diseases from other fields. The appropriateness of the research base will be determined by the initial review group. At least one of the Centers awarded in FY 96 will have a primary focus on studies related to inflammatory bowel disease.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details.

LETTER OF INTENT

Prospective applicants are asked to submit, by October 18, 1994, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDDK staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 594-7515
FAX: (301) 594-7503

APPLICATION PROCEDURES

Applications are to be submitted using form PHS 398 (rev. 9/91), available in the office of sponsored research at most academic or research institutions and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248. The RFA label available in the PHS 398 application form must be affixed to the bottom of the face page. Detailed instructions on submission procedures are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated by an appropriate peer review group convened by the NIDDK in accordance with the usual NIH peer review procedures. Following review, the applications will be given a second level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council unless not recommended for further consideration by the initial review group. Applications that are incomplete or unresponsive to the RFA will be returned to the applicant. Review Criteria are given in the RFA.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential are welcome. It is imperative that the pamphlet "Administrative Guidelines for Silvio O. Conte Digestive Diseases Research Core Centers" be obtained before an application is prepared. Requests for the RFA and the pamphlet and inquiries regarding programmatic issues may be directed to:

Dr. Judith M. Podskalny
Division of Digestive Diseases and Nutrition
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A15
Bethesda, MD 20892
Telephone: (301) 594-7539
FAX: (301) 594-7504

Inquiries regarding fiscal matters may be directed to:

Ms. Nancy Dixon
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 637A
Bethesda, MD 20892
Telephone: (301) 594-7543
FAX: (301) 594-7494

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.848. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SEXUALLY TRANSMITTED DISEASES COOPERATIVE RESEARCH CENTERS

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: AI-94-016

P.T. 34; K.W. 0715182, 0710030, 0785055

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: August 5, 1994

Application Receipt Date: November 17, 1994

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The purpose of this RFA is to stimulate multidisciplinary, collaborative research to further understanding of sexually transmitted diseases (STDs) and effective approaches to their prevention and control. The Sexually Transmitted Diseases Branch of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) invites research grant applications for recompetition of the Sexually Transmitted Diseases Cooperative Research Centers (STD CRCs). The NIAID recognizes that although each STD presents unique diagnostic, therapeutic, and prevention challenges, all STDs share a common mode of transmission, populations at risk for one STD are at risk for others, comorbidity is common, and the presence of one infection may influence the acquisition and natural history of another. Therefore, a research program that addresses these diseases as a group is likely to be highly productive. The CRCs provide a multi-disciplinary approach to STD research by bridging biomedical, clinical, behavioral, and epidemiological research areas; foster interaction among STD investigators; and facilitate intervention-oriented research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Sexually Transmitted Diseases Cooperative Research Centers (STD CRCs), is related to the priority areas of STDs and acquired immunodeficiency syndrome (AIDS). Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications will be limited to domestic institutions, but may include an international component. Applications may be submitted by domestic for-profit and non-profit research institutions; public and private organizations, such as universities, colleges, hospitals, laboratories, units of State or local governments; and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The administrative and funding mechanism to be used to undertake this program will be the Cooperative Agreement (U19). Details on the responsibilities, relationships, and governance of a study funded under a cooperative agreement are discussed in the RFA under the section Terms and Conditions of Award.

FUNDS AVAILABLE

The estimated total funds (direct and indirect costs) available for the first year of support for awards under this RFA will be \$6.2 million. In Fiscal Year 1995, the NIAID plans to fund five new and/or competing STD CRCs or more if additional money becomes available. This level of support is dependent on the receipt of sufficient number of applications of high scientific merit. The initial year's total costs, including direct and indirect costs, should not exceed \$1.2 million for each award. Each award will be made for a project period of four years. Funding beyond the first and subsequent years of the award will be contingent upon satisfactory progress during the preceding years and availability of funds.

RESEARCH OBJECTIVES

The purpose of this RFA is to stimulate multidisciplinary, collaborative research to further the understanding of STDs and effective approaches to their prevention and control. This will be accomplished through collaborations of scientists from various disciplines of biomedical, clinical, behavioral, and epidemiological research areas.

In addition to utilizing a multi-disciplinary approach, applications should include:

- o at least three projects, one of which should be in behavioral or epidemiologic research (behavioral/epidemiologic

research must include both behavioral or epidemiologic outcomes and microbiologic/disease outcomes);

- o two projects that link disciplines within a single scientific area (e.g., molecular biology and immunology within the biomedical area) and at least one project that links disciplines in two different areas (e.g., microbiology from the biomedical area and psychology from the behavioral area);

- o a strong clinical capability with accessible patient populations to participate in the clinical and behavioral/epidemiologic research projects;

- o provisions for the Principal Investigator of each CRC to attend meetings with NIAID staff twice each year and for all CRC Project Leaders to attend CRC workshops twice during the program period.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research." See the RFA for details. Copies of these Guidelines may be obtained from Dr. Miller listed in INQUIRIES below.

LETTER OF INTENT

Prospective applicants are asked to submit, by August 5, 1994, a letter of intent that includes a descriptive title of the overall proposed research; the name, address, and telephone number of the Principal Investigator; the number and title of this RFA; and a list of the key investigators and their institution(s). The letter of intent is to be sent to Dr. Olivia Preble at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Applications are to be submitted on the standard research grant application form PHS 398 (rev. 9/91). For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number and the words "SEXUALLY TRANSMITTED DISEASES COOPERATIVE RESEARCH CENTERS (STD CRCs)" must be typed in. The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. These forms may be obtained from the institution's office of sponsored research or its equivalent and from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248.

Applications must be received by November 17, 1994. All components, subparts and sections of the application must be collated into the application, and the packages sent to the DRG and to the NIAID must each be complete in themselves. Applications that do not conform to the instructions contained in PHS 398 (rev. 9/91) application kit will be judged nonresponsive and will be returned to the applicant.

REVIEW CONSIDERATIONS

Applications will be reviewed by the Division of Research Grants (DRG) for completeness and by NIAID for responsiveness to the RFA. Incomplete and non-responsive applications will be returned to the applicant without further consideration. The applications may be subjected to triage by a peer review group. The NIAID will remove from further competition those applications judged to be noncompetitive for award and will notify the applicant. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by a committee convened by NIAID. A second level of review will be provided by the NIAID Advisory Council.

AWARD CRITERIA

Funding decisions will be made on the basis of scientific and technical merit as determined by peer review, program priorities and balance, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcomed. Direct inquiries regarding programmatic issues and requests for the RFA to:

Dr. Heather Miller
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Solar Building, Room 3A-26
Bethesda, MD 20892
Telephone: (301) 402-0443
Internet Address: heather@exec.niaid.pc.niaid.nih.gov

Direct inquiries regarding review issues, address the letter of intent to, and mail two copies of the application and all five sets of appendices to:

Dr. Olivia Preble
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4C-20
Bethesda, MD 20892
Telephone: (301) 496-8208
Internet Address: op2t@nih.gov

Direct inquiries regarding fiscal matters to:

Ms. Katherine Phillips
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Solar Building, Room 4B-33
Bethesda, MD 20892
Telephone: (301) 496-7075

Schedule

Letter of Intent Receipt Date: August 5, 1994
Application Receipt Date: November 17, 1994
Scientific Review Date: February/March 1995
Advisory Council Date: June 1995
Earliest Award Date: July 1, 1995

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.855 Immunology, Allergic and Immunological Diseases Research and 93.856 Microbiology and Infectious Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of the Executive Order 12372 or Health Systems Agency review.

INSTITUTIONAL DENTIST SCIENTIST AWARD

NIH GUIDE, Volume 23, Number 18, May 13, 1994

RFA AVAILABLE: DE-94-005

P.T. 34; K.W. 0715148, 0710030

National Institute of Dental Research

Letter of Intent Receipt Date: December 1, 1994
Application Receipt Date: January 18, 1995

THIS IS A NOTICE OF AVAILABILITY OF A REQUEST FOR APPLICATIONS (RFA); IT IS ONLY AN ABSTRACT OF THE RFA. POTENTIAL APPLICANTS MUST REQUEST THE COMPLETE RFA, WHICH CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION, FROM THE CONTACT LISTED IN "INQUIRIES," BELOW. FAILURE TO FOLLOW THE INSTRUCTIONS IN THE COMPLETE RFA MAY RESULT IN AN INCOMPLETE APPLICATION, WHICH WILL BE RETURNED TO THE APPLICANT WITHOUT REVIEW.

PURPOSE

The National Institute of Dental Research (NIDR) invites applications proposing new and competing renewal Institutional Dentist Scientist Award programs in basic biomedical, behavioral and clinical oral health research. The purpose is the development of outstanding clinician research scientists. Programs must provide doctoral (Ph.D.) basic science and advanced clinical knowledge and skills development in either a recognized clinical specialty or other equivalent dental clinical discipline, and a supervised research experience designed to facilitate transition to an active research career. Programs must be relevant to the NIDR's goals.

Several changes have been introduced in the policies and provisions governing these awards. Current policies and provisions will remain in effect for all programs through June 30, 1995, and will continue to apply to appointees accepted into programs prior to that date until completion of their five years career development. The new policies and provisions will apply to appointments made on or after July 1, 1995 and to all new and competing renewal awards made on or after July 1, 1996.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000", a PHS-led national activity for setting priority areas. This RFA, Institutional Dentist Scientist Award, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, public and private dental schools, or institutions with a dental school affiliation. Only one award will be made to an institution.

Dentist Scientist Appointees (DSAs) to the programs must have a dental degree (D.D.S. or equivalent) and must be, at the time of appointment, citizens or noncitizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence.

Dentists who have completed a Ph.D. or equivalent research degree and those who have undergone clinical knowledge and skills development in a recognized dental specialty or who have received two or more years of formal postdoctoral clinical development in a non-specialty recognized clinical field are not eligible. They should apply for an individual Dentist Scientist Award (K15). Dentists who have undergone clinical development in either an Advanced Program in General Dentistry or a General Practice Residency Program are eligible.

MECHANISM OF SUPPORT

Awards resulting from this RFA will be National Institutes of Health (NIH) Institutional Dentist Scientist Awards (K16). Responsibility for planning, direction, and execution of the proposed program will be solely that of the program director on behalf of the applicant institution. The project period must be five years. The earliest award date is July 1, 1996.

FUNDS AVAILABLE

The NIDR expects to make at least six new or competing renewal awards, in response to this RFA, at a total first year cost of approximately five million dollars.

DSAs will receive salary and fringe benefits, research and development support for tuition, fees, research project expenses, travel and other purposes directly related to their training. The program director will receive partial salary support.

RESEARCH OBJECTIVES

Background

This award prepares individuals for careers as highly skilled investigators and potential leaders in oral health research. It provides for five years of intensive study, involving three distinct phases that include basic and clinical science components integrated with a supervised research experience. The basic science component includes didactic and laboratory experiences and is comparable to a program leading to a Ph.D. The research program employs either basic or clinical science approaches to an oral health problem. The program provides advanced clinical knowledge and skills development of the caliber that the individual would be eligible to receive specialty certification. Throughout the entire program, the individuals are closely supervised by mentors who have basic science, research and clinical specialty career development experience.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

Awards for research involving human subjects must follow the "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research."

LETTER OF INTENT

Prospective applicants are asked to submit, by December 1, 1994, a letter of intent that includes a descriptive title of the proposed Dentist Scientist Award program, the name, address, and telephone number of the PD, the identities of other key personnel, participating institutions, and the number and title of the RFA (RFA: DE-94-005, Institutional Dentist Scientist Award) in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows NIDR staff to estimate the potential review workload and to avoid conflicts of interest in the review.

The letter of intent is to be sent to Dr. Thomas M. Valega at the address listed under INQUIRIES.

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact Dr. Valega early in the planning phase of application preparation. Such contact may help ensure that applications are responsive to this RFA. Applications are to be submitted on form PHS 398 (rev. 9/91). Application forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248; and from Dr. Valega at the address listed under INQUIRIES.

Applications must be received by January 18, 1995.

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness and responsiveness to the RFA by NIH staff. Incomplete or nonresponsive applications will be returned to the applicant without further consideration. Remaining applications may be subjected to triage by an initial review group, convened by the NIDR Scientific Review Section, to determine their merit, relative to others received in response to the RFA. The NIDR will withdraw applications judged to be noncompetitive and notify the applicant and institutional official. Applications judged to be competitive will receive further review for scientific and technical merit by the review committee. Secondary review will be by the National Advisory Dental Research Council.

Additional review criteria are listed in the RFA.

AWARD CRITERIA

The earliest award date will be July 1, 1996. Funding decisions will be based on the initial review committee's and Council's recommendations, the need for research personnel in specific program areas, and the availability of funds.

INQUIRIES

Written and telephone requests for the RFA and inquiries concerning this RFA are encouraged. The opportunity to clarify any issue or questions from potential applicants is welcome. Direct requests for the RFA, inquiries on programmatic issues, and address the letter of intent to:

Thomas M. Valega, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 594-7617
FAX: (301) 594-7616

Direct inquiries on fiscal matters to:

Ms. Theresa Ringler
Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

Institutional Dentist Scientist Awards are made under the authority of Title III, Section 301 of the Public Health Service (PHS) Act as amended (Public Law 78-410, as amended, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 part 74, are applicable to this program. This program is also described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

INDIVIDUAL DENTIST SCIENTIST AWARD

NIH GUIDE, Volume 23, Number 18, May 13, 1994

PA NUMBER: PAR-94-065

P.T. 34; K.W. 0715148, 0710030

National Institute of Dental Research

PURPOSE

The National Institute of Dental Research (NIDR) re-announces the availability of individual Dentist Scientist Awards in basic biomedical, behavioral and clinical oral health research, which were initiated nine years ago. Several changes have been introduced in the policies and provisions governing these awards, which are effective for applications for the June 1, 1994, and later receipt dates and will apply to all appointments made on or after March 1, 1995. Dentists previously eligible for Physician Scientist Awards for Dentists (K11), now are eligible for K15s. The NIDR will no longer accept K11 applications. Existing policies and provisions will remain in effect for current appointees until completion of their five years career development. This Program Announcement (PA) supersedes all previous K11 and K15 announcements.

The purpose of the K15 is to develop outstanding clinician research scientists. It will provide doctoral (Ph.D.) basic science and research experiences to facilitate transition to a research career. Advanced clinical knowledge and skills development in a recognized clinical specialty or equivalent discipline, will be provided for Dentist Scientist appointees (DSAs) who have not undergone such development. It is anticipated that most graduates will undertake two or more years of post-Ph.D. research development to complete their preparation for an independent research career.

Research career development must be relevant to the goals of the NIDR including: research on the causes, epidemiology, prevention, diagnosis and treatment of dental caries, periodontal and soft tissue diseases, oral cancer, oral manifestations of AIDS, and craniofacial anomalies; orofacial pain; temporomandibular disorders; structure and function of teeth, jaws, oral mucosa, bone, connective tissue, salivary glands; behavioral, social, economic and cultural factors related to oral diseases and disorders; biomaterials; fluoride and nutrition; and research on older Americans, gender differences, minorities, those with medical problems and handicaps, and individuals and groups at high-risk for oral health problems.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Individual Dentist Scientist Award, is related to the priority area of oral health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary: Stock No. 017-001-00473-1) from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202/783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted on behalf of dentists, by domestic, public or private dental schools or institutions affiliated with a dental school. Minorities and women are encouraged to apply. Applicants must be U.S. citizens or noncitizen nationals, or have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551). Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are generally born in lands which are not states but are under U.S. sovereignty, jurisdiction, or administration. Dentists on temporary or student visas are not eligible.

Applicants holding a D.D.S. or equivalent degree are eligible. Preference will be given to applicants with advanced

clinical knowledge and skills in a recognized dental specialty or who have received two or more years of formal post-D.D.S. clinical development in a non-specialty recognized field. Dentists without advanced clinical knowledge and skills are eligible but are encouraged to seek appointment to NIDR sponsored institutional Dentist Scientist Award (K16) programs. Dentists with advanced clinical knowledge and skills, but wishing to develop such competence in another clinical area, those without or not wishing to pursue clinical knowledge and skills development, and those with a Ph.D. in another area may request the NIDR to consider their eligibility.

Former principal investigators on NIH research project (R01), FIRST (R29), sub-projects of program project (P01) or center grants (P50), or the equivalent, are not eligible.

MECHANISM OF SUPPORT

Awards in response to this PA will use the NIH K15. Planning, direction, and execution of the program will be the responsibility of the DSA and mentor on behalf of the applicant institution. The project period must be five years. Awards are not renewable.

RESEARCH OBJECTIVES

A. Environment: The institution must have well-established research and clinical career development programs and qualified faculty in clinical and basic research to serve as mentors. The DSA, mentor and institution must develop innovative multidisciplinary programs to maximize the available research and educational resources.

B. Program: The award provides five consecutive 12 month appointments. At least 80 percent of the DSA's effort must be devoted to the program and the remainder devoted to other clinical and teaching pursuits consonant with the objectives of the award.

The program must meet the unique needs of the DSA and provide requisite competencies. There will be two or three distinct, integrated components: basic science, supervised research, and, for some, advanced clinical knowledge and skills development. No component can be offered in isolation from the other(s). The basic science component must develop knowledge and research skills in scientific areas relevant to oral health and include didactic and laboratory experiences consistent with the applicant institution's Ph.D. requirements and the objectives of the award. The research experience must use basic or clinical approaches to oral health problems, comparable to a doctoral program. The advanced clinical development must ensure acquisition of clinical knowledge and skills in either a recognized clinical specialty or equivalent dental clinical discipline. These are not limited to the eight dental specialties recognized by the American Dental Association. If specialty certification is possible, the certificate is not to be conferred until program completion.

C. Mentor(s): The DSA must be closely supervised throughout the five year program by mentors with basic and clinical specialty research and career development experience. The primary mentor is usually the doctoral thesis advisor. Where feasible, women and minority mentors should be involved as role models.

D. Duration, Effort, and Allowable Costs:

1. Salary: The NIDR will provide salary up to the amounts listed below, starting at \$26,500 for 0 years relevant experience, with four percent annual increases thereafter, up to a maximum of \$39,226. The salary must not exceed institutional salaries provided from its own funds to other staff or faculty with equivalent qualifications, rank, and responsibility in the department concerned. Fringe benefits will be provided. The scale extends up to 10 years to give credit for relevant postdoctoral experience including: research, including industrial; teaching; residency; clinical practice; or time spent in a health-related field beyond the doctoral degree.

| Number of Years Experience | Salary (maximum provided by the NIDR) |
|----------------------------|---------------------------------------|
| 0 | \$26,500 |
| 1 | \$27,560 |
| 2 | \$28,662 |
| 3 | \$29,808 |
| 4 | \$31,000 |
| 5 | \$32,240 |
| 6 | \$33,530 |
| 7 | \$34,871 |
| 8 | \$36,266 |
| 9 | \$37,717 |
| 10 or more | \$39,226 |

Salaries may be supplemented from non-Federal funds. Other NIH funds may not provide additional salary. Non-NIH Federal funds may not supplement salary unless authorized under terms of the program. An individual may use Federal educational loan funds or Department of Veterans' Affairs benefits when permitted by those programs. Under no circumstance may the condition of salary supplementation detract from or prolong the program.

2. Provisions must be made for support of a DSA choosing clinical specialties that require more than two years of clinical knowledge and skills development.

3. Research Development Support (RDS): \$15,000 per year will be allowed for the following expenses: (a) tuition, fees, and books related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) DSA travel to research meetings or training; (d) statistical services including personnel and computer time. Authorization to use RDS funds for other purposes may be requested from the NIDR.

4. Authorization may be requested from the NIDR to carry over unobligated funds from one budget period to the next; for example, for support of a DSA's salary and RDS for up to 12 months beyond the standard five years to permit completion of the program.

5. Ancillary Personnel Support: Salary for mentors, secretarial and administrative assistance, etc., is not allowed.

6. Indirect costs - reimbursement of actual indirect costs at a rate up to, but not exceeding, eight percent of the total direct costs, exclusive of tuition, fees and equipment, is allowed.

E. Concurrent Awards: DSAs are encouraged to seek support for a post-Ph.D. experience after completion of the K15 program, ideally at another institution. During the final one to two years of their program, they may apply for a post-Ph.D., National Research Service Award (NRSA) individual fellowship (F32), apply for appointment to a NIDR sponsored NRSA institutional postdoctoral training program (T32), or arrange for other support from the NIH or from nongovernmental sources sufficient to ensure two or more years of post-Ph.D. training and career development. If such support becomes effective prior to completion of the K15 program, it may be used without reduction in the annual RDS from the award.

F. Evaluation: For ten years after leaving the program, the DSA and mentor must update the NIDR annually of the DSA's employment history, publications, participation in research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 9, 1994 (FR 59 11146-11151), and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Investigators may obtain copies from these sources or from the program staff or contact person listed below. Program staff may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact Dr. Valega at the address listed under INQUIRIES early in the planning phase of application preparation. Such contact may help ensure that applications are responsive to this PA.

Applications are to be submitted on form PHS 398 (rev. 9/91) and will be accepted on or before the receipt deadlines indicated in the application kit (February 1, June 1, and October 1). Forms are available at most institutional offices of sponsored research; the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone (301) 594-7248, and from Dr. Valega.

Provide information establishing a serious commitment to oral health research and a high potential to develop into an independent investigator. Summarize immediate and long-term career objectives, explaining how the award would contribute to their attainment. Include three sealed letters of recommendation addressing the applicant's potential for a research career.

Describe the basic science component, including didactic and laboratory experiences, and arrangements for acceptance in the graduate school doctoral program. The research experience may use a basic or clinical science approach to oral health problems.

When appropriate, describe the advanced clinical component to acquire knowledge and skills in either a recognized clinical specialty or other equivalent dental clinical discipline. Indicate clinical disciplines and degree certifications to be pursued. Selections may not be changed without NIDR approval.

The applicant and mentor together must describe the research plan as outlined on pages 19-24 of form PHS 398, Specific Aims, Background and Significance, Progress Report/Preliminary Studies, Research Design and Methods. Typically, it is what is required for a doctoral degree. The plan should be as detailed as possible, especially for applicants who will not be pursuing the advanced clinical component. Applicants who will be pursuing the clinical component, where it may be premature to provide detailed plans, must discuss the area, feasibility, relevance, and significance of the anticipated research. In this case, the DSA will be required to submit, for NIDR approval, a detailed description of the proposed research as soon as feasible after appointment but no later than the midpoint of the program.

Applications must include plans for instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction; and the amount and nature of faculty participation. No award will be made if an application lacks this component.

Budget requests must be provided according to the instructions in form PHS 398. The RDS requested for tuition and fees, books, travel, etc., must be specified by category.

To identify the application as a response to this PA, check "YES" on item 2a of page 1 of the application and enter "PA-94-065, Individual Dentist Scientist Award."

Submit a signed, typewritten original of the application with Checklist, and three signed photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892-4500**

At the time of submission, two additional copies, together with three sealed letters of reference, must be sent to:

H. George Hausch, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 519
Bethesda, MD 20892
Telephone: (301) 594-7632

REVIEW CONSIDERATIONS

Applications will be reviewed for completeness, and responsiveness to the PA, by NIDR staff. Incomplete or nonresponsive applications will be returned to the applicant without further consideration. Remaining applications may be subjected to triage by the NIDR Special Grants Review Committee to determine their merit, relative to others received in response to the PA. The NIDR may withdraw applications judged to be noncompetitive and notify the applicant. Applications judged to be competitive will be evaluated for scientific and technical merit by the review committee. The following review criteria will be applied:

- o Applicant: Clinical and scientific knowledge and experience; potential and commitment to a career as an independent researcher.
- o Environment: Institutional commitment and ability to provide research development opportunities; collaboration between basic and clinical departments; availability of facilities, equipment, clinical resources and research support.
- o The Basic Science, Clinical and Research Career Development Program: Its structure and the quality of each component; integration of the components; relationships among clinical and basic science departments and the graduate school in the design and conduct of the program; degree requirements; types of specialty development; availability of prescribed and optional courses or seminars; procedures for selecting research activities and monitoring progress; and the unique and innovative aspects of the program.
- o Mentors: Experience in graduate research and clinical career development; accomplishments in research; and current and pending research grant holdings; time commitment for the duration of the program.
- o Responsible Conduct of Research: The quality of instruction.

Secondary review will be by the National Advisory Research Council.

AWARD CRITERIA

The NIDR will notify the applicant of the Council's action shortly after its meeting. Funding decisions will be made based on the Special Grants Review Committee's and Council's recommendations, the need for research personnel in specific program areas, and the availability of funds. Preference will be given to otherwise equally qualified applicants with advanced clinical certification. The NIDR appreciates the value of complementary funding from other public, foundation and industry sources, for activities that will complement and expand those supported by the NIDR.

INQUIRIES

Written and telephone inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries on programmatic issues to:

Thomas M. Valega, Ph.D.
Extramural Program
National Institute of Dental Research
Westwood Building, Room 503
Bethesda, MD 20892
Telephone: (301) 594-7617
FAX: (301) 594-7616

Direct inquiries on fiscal matters to:

Ms. Theresa Ringler
Extramural Program
National Institute of Dental Research
Westwood Building, Room 510
Bethesda, MD 20892
Telephone: (301) 594-7629

AUTHORITY AND REGULATIONS

Individual Dentist Scientist Awards are made under the authority of Title III, Section 301 of the Public Health Service (PHS) Act as amended (Public Law 78-410, as amended, 42 USC 241). The Code of Federal Regulations, Title 42 Part 52, and Title 45 part 74, are applicable to this program. This program is described in the Catalog of Federal Domestic Assistance No. 93.121. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MEDICAL TREATMENT EFFECTIVENESS RESEARCH -- PORT-II

NIH GUIDE, Volume 23, Number 18, May 13, 1994

PA NUMBER: PA-94-066

P.T. 34; K.W. 0730050

Agency for Health Care Policy and Research

PURPOSE

The Agency for Health Care Policy and Research (AHCPR) invites applications for innovative and timely research that will provide convincing evidence for or against the effectiveness and/or cost effectiveness of alternative clinical interventions used to prevent, diagnose, treat, and manage common clinical conditions. "PORT-IIs" will extend the work of AHCPR's original Patient Outcomes Research Teams (PORTs) into more clinical areas and will make substantial new contributions to improved patient outcomes, clinical practice, and health care policy. Awards will be part of the new generation of research developed by AHCPR for the Medical Treatment Effectiveness Program (MEDTEP), as introduced in Request for Applications (RFA) HS-94-002.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. The AHCPR urges applicants to submit grant applications with relevance to the specific objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-004374-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit organizations, public and private, including universities, clinics, units of State and local governments, non-profit firms, and non-profit foundations. Applications from minority and women investigators are encouraged.

MECHANISM OF SUPPORT

This program announcement (PA) uses the research project grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

The total requested project period may not exceed five years. Annual progress reviews by AHCPR and the availability of funds will determine the continuation of grants up to the five year limit.

RESEARCH OBJECTIVES

Background and Conceptual Framework

Since 1989, AHCPR has made a major investment and major advances in medical effectiveness research, especially through the set of special projects known as PORTs. This PA describes a new generation of PORT research, introduced in July 1993 with RFA HS-94-002. Like the original PORTs, PORT-IIs are pragmatic, methodologically sophisticated, multidisciplinary projects that focus on patient outcomes for common clinical problems and emphasize the policy significance of understanding what health care services and procedures are most effective and for whom.

PORT-IIs are expected to start with careful formulations of important research questions about the effectiveness and relative effectiveness of different clinical approaches to common conditions. The proposed research strategy must be tailored to the research question(s) and the population at risk; unlike the original PORT projects, PORT-IIs do not have a common research plan. PORT-IIs focus on the establishment of direct linkages between clinical practice and outcomes, and on research methods and data that facilitate direct comparisons of different clinical strategies available for use in routine practice. PORT-IIs do not test or evaluate the application of clinical practice guidelines or "appropriateness criteria;" rather, they are designed to obtain empirical evidence useful for constructing, specifying, and updating such guidelines.

PORT-IIs incorporate fundamental concepts of all MEDTEP research, as defined below.

"Effectiveness" refers to the outcomes experienced by, or observed in, typical patients receiving care in typical clinical situations. The intent of this emphasis is to ensure that the findings of all PORT-IIs can be widely generalized. "Patient outcomes" are the terms in which effectiveness and cost effectiveness are assessed. Outcomes of interest emphasize the patient's perspective. They include survival, symptom relief, patient-reported quality of life, functional status, satisfaction with care, and costs. In PORT-IIs, analysis of a broad set of outcomes is generally desirable. It is essential that the analysis include the most significant outcomes for the particular condition under study, both long- and short-term.

"Cost effectiveness" is the comparison of the direct monetary costs of health care plus the indirect costs (e.g., lost work) associated with the outcomes of the intervention. PORT-IIs should address questions of cost effectiveness if or when the interventions to be compared are likely to be associated with significant differences in cost or outcome.

In analyzing effectiveness and cost effectiveness, PORT-IIs take into account the many important clinical and non-clinical variables that influence practice and outcomes. This includes pertinent characteristics of patients (e.g., comorbidities; medical history; demographic, socioeconomic, and cultural characteristics; preferences and utilities); providers (e.g., training, skill, practice style); diseases (e.g., severity, course); and the health care system (e.g., setting, type of practice, liability issues).

Topic Selection

PORT-II studies will be condition-specific or technology-specific, and will conduct comparative analyses of the most important alternatives for prevention, diagnosis, treatment, and/or management. A well-defined disease (e.g., breast cancer, pediatric asthma) or a symptom or condition (e.g., headache, fatigue, obesity) may be selected. The topic must meet all of the following MEDTEP criteria:

- o high incidence or prevalence in the general population or in major population subgroups, as defined by age, gender, or ethnicity;
- o controversy or open questions over the effectiveness and relative effectiveness of available clinical strategies; and
- o high cost whether due to the number of people needing care, high unit cost of care, or high indirect cost.

Applicants are expected to present a strong case for their selected topic in a critical literature review that: addresses the clinical, policy, and research significance of the topic; provides evidence of controversy or information gaps regarding current clinical strategies; and supports the formulation of the proposed research question(s). The formulation of the problem must reflect understanding of the issues regarding clinical decisionmaking and the translation of study findings into clinical practice. Further, the research questions must be answerable within the proposed grant period.

PORT-IIs are expected to compare distinctly different clinical approaches to the prevention, diagnosis, treatment, or management (including rehabilitation) of common clinical conditions. Examples of responsive studies include comparisons of: medical vs. surgical treatment; treatment vs. watchful waiting; psychotherapy vs. pharmacotherapy; or invasive vs. non-invasive screening technologies. Other possible comparisons include care prescribed or provided by different kinds of health care professionals, or in different care settings. If it is not feasible to address all important treatment options in a single study, applicants must identify the specific interventions the study will address and justify the selections and exclusions. In general, the most comprehensive assessments of pertinent clinical strategies will be of greatest interest for PORT-IIs.

Methods

Investigators are encouraged to design new research strategies, use new combinations of methods, or tailor existing methods to their research questions so that convincing evidence will be obtained for or against the effectiveness of alternative clinical interventions.

PORT-IIs may employ experimental, quasi-experimental, or observational designs; methods include, but are not limited to, case-control studies, cohort studies, clinical trials, meta-analyses, cost effectiveness analyses, decision modeling, and combinations of these methods. MEDTEP's emphasis on the generalizability of results precludes traditional randomized controlled trials (RCTs) whose findings of "efficacy" apply only to narrowly defined patient groups and circumstances. PORT-IIs do, however, include "effectiveness trials," designed to answer questions about the likely outcomes of health care in the "real world." Thus, randomized studies that include a broad range of patients and practitioners are encouraged.

Types and sources of data may include clinical, patient-reported, and administrative data. The data may be obtained prospectively or retrospectively from registries or records of health care providers, or via new, established, or adapted surveys of patients and health care providers. Primary data will generally be required; however, these may be combined with, and occasionally replaced by, secondary data when the latter will provide adequate information and an efficient means to address the research questions. For example, administrative data, although they generally lack clinical detail, may be useful in identifying cases and controls, estimating costs, or measuring some outcomes.

Applicants who propose to use Medicare or Medicaid data must specify the required data files and explore the availability and cost of obtaining these data with the Health Care Financing Administration (HCFA). The estimated cost must be presented along with documentation from HCFA, as part of the grant application. This cost should not be included in the total budget request for the project. For more information about data budgets, contact Ralph L. Sloat, AHCPR Grants Management Officer; at the address listed under INQUIRIES.

The application must be explicit and detailed in justifying the proposed methods and data in terms of their potential for answering the research questions under study and the generalizability of results. Descriptions of the data collection and analysis plans, including strategies for case-finding, measuring outcomes, and comparing alternative treatments, must be specific. Adequate attention must be paid to relevant characteristics of:

- o the population at risk for the condition,
- o the condition,
- o the clinical interventions,
- o the outcomes,
- o the providers,
- o available data and measures, and
- o the sociocultural context of illness and health care.

Project Organization

To address the clinical and non-clinical dimensions of effectiveness research, PORT-IIs will require multidisciplinary research teams. The composition of the team and relative time commitments of each member should be well justified in terms of substantive knowledge, methodological expertise, and experience in conducting or managing related research projects. Each team should include at least one individual who is actively involved in patient care central to the study, and who contributes understanding of how and why clinical decisions are made in routine clinical practice.

Applicants are encouraged to take full advantage of opportunities for efficient enhancements of available expertise, data, and other resources. This might include collaboration with researchers and practitioners outside applicants'/'

grantees' own institutions, creative use of existing data, or "piggybacking" on other research activities. In addition, existing practice variations that are known to exist across health care settings, systems, or international borders can provide special opportunities for comparative analysis of outcomes.

STUDY POPULATIONS

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of AHCPR that women and members of minority groups must be included in all AHCPR supported health services research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

A new NIH policy resulting from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) supersedes and strengthens NIH's previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which were in effect since 1990 and which AHCPR had adopted. The new NIH policy contains some provisions that are substantially different from the 1990 policies. AHCPR plans to publish guidelines specific to AHCPR. In the interim, AHCPR will follow the NIH guidelines, as applicable.

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the Federal Register of March 9, 1994 (FR 59 11146-11151) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the NIH policy from the AHCPR program staff listed under INQUIRIES. AHCPR program staff may also provide additional relevant information concerning this policy.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 9/91), and will be accepted at the standard application deadlines as indicated in the application kit. State and local government agencies may use form PHS 5161 and follow those requirements for copy submission. Application kits are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301-594-7248; and for AHCPR applications from Global Exchange Inc., 7910 Woodmont Ave Suite 400, Bethesda, MD 20814-3015, telephone 301-656-3100 (FAX 301-652-5264).

The completed, signed, original application and five legible copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

The Division of Research Grants (DRG) will not accept any application in response to this program announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness. Incomplete applications will be returned to applicants without further consideration. General scientific review criteria are: significance and originality from a scientific and technical viewpoint; adequacy of the method(s); availability of data or adequacy of proposed plan to collect data; qualifications and experience of the principal investigator and proposed staff; adequacy of the plan for organizing and carrying out the project; reasonableness of the proposed budget; and adequacy of the facilities and resources available to the applicant.

Each PORT-II application will be independently evaluated for scientific/technical merit in accordance with the general criteria stated above and the special scientific review criteria listed below, by an appropriate peer review group. Applications assigned to the AHCPR requesting direct costs, over the life of the project, exceeding \$250,000 will be reviewed by AHCPR's National Advisory Council for Health Care Policy, Research, and Evaluation, as may applications requesting direct costs, over the life of the project, in excess of \$50,000.

Special Scientific Review Criteria

The major scientific criterion for evaluating PORT-II applications assigned to the AHCPR is the potential for obtaining convincing, new evidence for the effectiveness or ineffectiveness of health care services and procedures. The topic must be compatible with the MEDTEP criteria listed under Topic Selection. Other special criteria are:

- o scientific importance and policy relevance of the clinical topic and the particular clinical interventions to be studied, as justified in a review of the literature;
- o generalizability of results;
- o feasibility of answering the proposed research question(s) within the project period;
- o attention to technical issues in case-definition, case-finding, data collection, and analysis;
- o quality and adequacy of the proposed data;
- o justification for focus on the outcomes specified;

- o adequacy of outcomes measures, including costs if applicable;
- o extent to which research design permits direct comparisons of treatment effectiveness and/or cost effectiveness;
- o evidence of understanding of the issues in clinical decisionmaking and the translation of research findings into clinical practice;
- o sensitivity to patient heterogeneity and individual preferences;
- o specification of useful findings or products and identification of constituency(ies) for these;
- o efficiency of the research plan; and
- o evidence of productive collaborations (e.g., with other institutions, appropriate professional groups, other sources of support).

AWARD CRITERIA

Applications will compete for available funds with all other investigator-initiated applications. In making funding decisions, AHCPR will consider: quality of the proposed project as determined by peer review, availability of funds, and program balance. The earliest anticipated date of award is nine months from the date of submission.

INQUIRIES

Those considering applying in response to this PA are strongly encouraged to discuss their project with AHCPR program administrators before formal submission. The AHCPR welcomes the opportunity to clarify any issues or questions from potential applicants.

Direct inquiries regarding programmatic issues, including information on the policy of inclusion of women and minorities in study populations, to:

Richard Greene, M.D., Ph.D.
Center for Medical Effectiveness Research
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 605
Rockville, MD 20852
Telephone: (301) 594-1485

Direct inquiries regarding fiscal matters to:

Ralph L. Sloat
Grants Management Office
Agency for Health Care Policy and Research
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-1447

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.180. Awards are made under authorization of the Public Health Service Act, Title IX, and Section 1142 of the Social Security Act. Awards are administered under the PHS Grants Policy Statement and Federal Regulations 42 CFR Part 67, Subpart A, and 45 CFR Part 74 (45 CFR Part 92 for State and local governments). This program is not subject to the intergovernmental review requirements of Executive Order 12372.

SUPPLEMENTS TO PROMOTE REENTRY INTO BIOMEDICAL AND BEHAVIORAL RESEARCH CAREERS

NIH GUIDE, Volume 23, Number 18, May 13, 1994

PA NUMBER: PA-94-067

P.T. 34; K.W. 0710030

National Institutes of Health

PURPOSE

The National Institutes of Health (NIH) announces a program for administrative supplements to research grants to support individuals with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other family responsibilities. The aim of these supplements is to encourage fully trained individuals to reenter research careers within the missions of the program areas of the NIH. This program will provide administrative supplements to existing NIH research grants for the purpose of supporting full-time or part-time research by these individuals in a program geared to bring their existing research skills and knowledge up to date.

The NIH recognizes the need to increase the number of women and minorities and people with disabilities in basic, behavioral, and clinical science research careers. Among the reasons for the low representation of women may be the fact that women bear a majority of the responsibilities surrounding child and family care. To address this issue, this program is designed to offer opportunities to women and men who have interrupted their research careers to care for children or parents or to attend to other family responsibilities. The objective of the program is for those who receive support to reestablish careers in biomedical or behavioral research.

In 1992 and 1993, the Office of Research on Women's Health sponsored a research supplement program to promote reentry with a single application date each year. The present program announcement replaces that program with one with an open receipt date and with review and funding directly by participating Institutes and Centers (ICs). Participating ICs are the National Cancer Institute, National Eye Institute, National Heart, Lung and Blood Institute, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development, National Institute of Dental Research, National Institute of Drug Abuse, National Institute of Environmental Health Sciences, National Institute of General Medical Sciences, National Institute on Deafness and Other Communication Disorders, National Center for Human Genome Research, and National Center for Research Resources. The National Institute of Mental Health (PA-94-043) recently announced a similar reentry supplement program. The National Institute of Neurological Disorders and Stroke previously announced a Research Career Development Award (K17) for scientists reentering the neurological sciences (NIH Guide, Vol. 21, No. 33, 1992).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement, Supplements to Promote Reentry into Biomedical and Behavioral Research Careers, is related to the priority area of women's health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Grants and Cooperative Agreements: Only the following active NIH award mechanisms at domestic institutions are eligible for Supplements to Promote Reentry into Biomedical and Behavioral Research Careers: R01, R10, R18, R24, R35, R37, P01, P40, P41, P50, P51, P60, U01, U10, and G12. Principal Investigators on such awards are invited to submit a request for an administrative supplement to the awarding component of the parent grant to support an eligible candidate interested in reestablishing a research career. The parent grant must have at least two years of support remaining at the time of the proposed beginning date of the supplemental funding. The rationale for this policy is to ensure ample opportunity for the candidate to develop further her or his research skills. A maximum of three years supplemental support can be awarded under this program. Usually, a parent grant would support only one administrative supplement (Research Supplements for Underrepresented Minorities, Research Supplements to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers, or Research Supplements to Promote Reentry into Biomedical and Behavioral Research Careers). Grants most likely to support more than a single administrative supplement are multicomponent awards.

Candidates

Candidates must have a doctoral degree, such as M.D., D.D.S., Ph.D., O.D., D.V.M., or equivalent, and at least two years of post-doctoral research experience and must have had sufficient prior research experience to qualify for a faculty appointment at the assistant professor or equivalent level. Candidates who have begun the reentry process through a fellowship or similar mechanism are not eligible for this program.

The following general guidelines will be applied by the individual ICs. In general, the duration of the career interruption should be for at least two years and no more than eight years. Examples of qualifying interruptions would include starting and/or raising a family, an incapacitating illness or injury of the candidate, the spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service. The program is not intended to support graduate or postdoctoral training and is not intended to support career changes from non-research to research careers for individuals without prior research training. Generally, at the time of application, a candidate may not be engaged in paid research activities for more than 25 percent effort.

MECHANISM OF SUPPORT

In all cases, the proposed research must be directly related to the funded approved ongoing research of the parent grant or cooperative agreement. The individual supported under this supplemental award, hereafter called the reentry candidate, must be afforded the opportunity to act as a full participant in the research project and must be given an opportunity to update and enhance her or his research capabilities. This will allow the candidate to begin the process of establishing or re-establishing a career as an independent, competitive research investigator. Supplemental awards will be consistent with the goals of strengthening the existing research program and with the overall programmatic balance and priorities of the funding program of the NIH. Awards will be made according to the policies and provisions stated in this announcement and in the PHS Grants Policy Statement (rev. 10/90).

Administrative supplements (S1) provided under this program may be for either part-time or full-time support for the candidate, and all supported time is to be spent updating and enhancing research skills. Proposed part-time appointments may not be less than 50 percent effort per week.

Supplemental awards may be made for up to three years and may not exceed \$50,000 in direct costs per year. A maximum of \$40,000 may be requested for the combination of full time salary and fringe benefits for the reentry candidate. The amount of salary requested must be consistent with the policies of the grantee institution for individuals occupying similar positions and must be related to the percent effort requested for the supplement and the number of months requested for the supplement. An additional amount up to \$10,000 may be requested for supplies, domestic travel, and publication costs relevant to the proposed research. Equipment may not be purchased as a part of this supplement without justification and specific prior approval of the NIH.

The decision to fund a supplement will take six to eight weeks from the time the necessary information is received by the awarding ICD. During the first budget period, funds will be provided as an administrative supplement to the parent grant. In subsequent years, continued funding for the supplement is contingent on funding of the parent grant and can not extend beyond the current competitive segment of the parent grant. A decision may be made to pay, but, in fact, at the end or beginning of a year, no funds may be available.

APPLICATION PROCEDURES

A request for a supplement may be made at any time during the funding year, providing there will be two full years of funding remaining for the parent grant at the time of funding. In making requests, the grantee institution, on behalf of the Principal Investigators, should submit the request for supplemental funds directly to awarding component that supports the parent grant. The request is NOT to be submitted to the NIH Division of Research Grants. Principal Investigators are encouraged to obtain the address for submission from the NIH program administrator on the parent grant.

The request for a supplemental award must include the following:

1. A complete face page (with appropriate signatures) from grant application form PHS 398 (rev. 9/91), including the title and grant number of the parent grant and "Reentry Supplement" on line 1
2. A brief, three- or four-page description, prepared by the Principal Investigator of the parent grant, that includes:
 - a. A summary or abstract of the funded grant or project
 - b. A description of the research proposed for the candidate
 - c. How the supplement will expand and foster the independent research capabilities of the candidate
 - d. How the proposed research relates to the specific research goals and objectives of the parent grant
 - e. A description of the scope and nature of the mentoring relationship between the Principal Investigator and the candidate
3. A brief description, prepared by the candidate, that includes:
 - a. research objectives and career goals
 - b. length of and reason for career hiatus
 - c. description of how the candidate has kept current or attempted to keep current in her/his field
 - d. identification of steps taken toward reentry, (if any, such as attending scientific meetings)
4. A biographical sketch of the candidate that includes:
 - a. curriculum vitae
 - b. social security number
 - c. citizenship status
 - d. publications
 - e. other evidence of scientific achievement.
5. A proposed budget entered on budget pages from the grant application form PHS 398 (rev. 9/91), related to the percent effort for the research proposed for the reentry candidate during the first and future budget period(s) (The amount requested for the supplement must coincide with the current period of support. Thus, if the initial budget period requested is less than 12 months, the budget must be prorated accordingly.)
6. Documentation, if applicable, that the proposed research is approved by the Institutional Animal Care and Use Committee (IACUC) or human subjects Institutional Review Board (IRB) of the grantee institution
7. Under unusual circumstances in which the applicant and mentor would be at a site other than the grantee institution, an appropriately signed letter from the institution where the research is to be conducted must also be submitted.

The request must be signed by the Principal Investigator, the reentry candidate, and the appropriate institution business official.

REVIEW CONSIDERATIONS

The program staff of the individual ICDs will review requests for supplements using the following general criteria:

- o the qualifications of the reentry candidate, including career goals, prior research training, research potential, and any relevant experience
- o the plan for the proposed research experience in the supplemental request and its relationship to the parent grant
- o evidence from the Principal Investigator that the experience will enhance the research potential, knowledge, and/or skills of the reentry candidate
- o evidence from the Principal Investigator that the activities of the reentry candidate are an integral part of the project
- o evidence of effort by the reentry candidate to initiate the reentry process, such as attending scientific meetings, keeping current with journals
- o evidence that proposed research will achieve the stated objectives of the reentry supplements

In noncompeting continuation applications, the progress report for the reentry supplement should be clearly delineated from the progress report for the parent grant. The progress report should include information about the research activities supported by the supplement, even if support for future years is not requested. Since these applications will undergo administrative review, summary statements will not be produced. This is consistent with NIH practice for other similar programs, such as those referenced in the ELIGIBILITY REQUIREMENTS section of this program announcement.

INQUIRIES

For general information about the reentry supplements, candidates and Principal Investigators should contact the program official of the appropriate awarding Institute or Center. Candidates who have not yet made contact with a Principal Investigator are encouraged to contact the program official whose institute or center is specific to the research interest. To discuss business aspects of the parent grant or the supplement, Principal Investigators should contact their grants management official. Program officials and grants management contacts and the respective awarding institutes or centers are listed below.

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AUTHORITY AND REGULATIONS

Supplemental awards will be made under authorities applicable to the parent grant and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

*****THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:***

***5333 Westbard Avenue
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